



**Randomised controlled trial of an education and support package for stroke patients and their carers**

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**Randomised controlled trial of an education and support package for stroke patients and their carers**

**Abstract**

**Objective:**

Tailoring stroke information and providing reinforcement opportunities are two strategies proposed to enhance the effectiveness of education. This study aimed to evaluate the effects of an education package which utilised both strategies on the knowledge, health and psychosocial outcomes of stroke patients and carers.

**Design:**

Multi-site, randomised trial comparing usual care with an education and support package

**Setting:**

Two acute stroke units

**Participants:**

Patients and their carers (N=138) were randomised (control n=67, intervention n=71) of which data for 119 participants (control n=59, intervention n=60) were analysed.

**Intervention:**

The package consisted of a computer-generated, tailored written information booklet and verbal reinforcement provided prior to, and for three months following, discharge.

**Outcome measures:**

Outcome measures were administered prior to hospital discharge and at three month follow-up by blinded assessors. The primary outcome was stroke knowledge (score range: 0-25). Secondary outcomes were: self-efficacy (1-10), anxiety and depression (0-21), ratings of importance of information (1-10), feelings of being informed (score range: 1-10), satisfaction with information (1-10), caregiver burden (carers) (0-13) and quality of life (patients) (1-5).

**Results:**

Intervention group participants reported better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention information (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ). There was no significant effect on other outcomes.

**Conclusions:**

Intervention group participants had improved self efficacy for accessing stroke information and satisfaction with information, but other outcomes were not significantly affected.

Evaluation of a more intensive intervention in a trial with a larger sample size is required to establish the value of an educational intervention that uses tailoring and reinforcement strategies.

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## Article summary

### Article focus:

- Patient and carer education is a crucial component of post-stroke care but little is known about the most effective way of providing it
- Tailoring stroke information and providing opportunities for reinforcement are recommended
- This study aimed to evaluate the effects of an education package which used both of these strategies on the knowledge, health and psychosocial outcomes of stroke patients and carers

### Key messages

- The education and support package included a computer-generated, tailored written information booklet and verbal reinforcement, provided in hospital and during the three months following discharge after stroke
- The package improved stroke self efficacy for accessing stroke information and satisfaction with information received.
- The effects of tailored messages and verbal reinforcement on other outcomes, such as knowledge, mood, quality of life/caregiver burden, is not known

### Strengths and limitations of this study

- This intervention evaluated in this study was theoretically informed, developed with patient and carer input, and built on previous trial results. Additionally, the inclusion of both patients and carers enhances the applicability to health professionals working in this clinical area (where patients are often seen with their carers or a family member)

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- Results may not be generalisable to all patients with stroke. There was also underpowering of some outcome measures and several outcome measures lack available psychometric data.

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## Introduction

Stroke information provision is a crucial component of care for patients and carers<sup>1-3</sup>, however their information needs are often poorly met<sup>4-8</sup>. Information needs vary between individuals<sup>9</sup> and tailoring of information to individual patient and/or carer needs is required<sup>10-13</sup>.

Three tailored written information interventions for patients with stroke have been evaluated in randomised trials<sup>14-16</sup>. In an evaluation of booklets that contained information previously presented verbally there were no significant differences in physical or social functioning between groups<sup>14</sup>. Evaluation of individualised information booklets that were verbally reinforced in one session found significantly better stroke knowledge for intervention group patients, but no other between-group differences<sup>15</sup>. In a trial which compared a computer-generated tailored written information booklet ('What you need to know about stroke') with generic non-tailored stroke information, intervention group patients had significantly better satisfaction with information received and their information needs were better met, but no other significant improvements compared to the control group<sup>16</sup>. These studies suggest that while there may be some benefits associated with tailored written information, refinement of tailored stroke educational interventions and further research is required.

A possible mechanism for enhancing the effectiveness of stroke information interventions is suggested in a Cochrane review, in which 'active' interventions (which actively included patients and carers and provided the opportunity to clarify and reinforce information) were found to be more effective at improving patient anxiety and depression than passive ones<sup>17</sup>. Furthermore, because patients and carers continue to have information needs after leaving hospital<sup>8, 18</sup>, continued access to information after discharge is recommended<sup>1</sup>.

In the current study, an education and support package for patients and carers that expanded upon the previously evaluated ‘What you need to know about stroke’ tailored booklet and provided opportunities for clarification and reinforcement of information both prior to, and following, discharge, was developed. Research into patients’ and carer’s information needs and format preferences<sup>19</sup> was also used to inform the intervention design. The aim of this study was to evaluate the effect of this education package on the knowledge, health and psychosocial outcomes of stroke patients and carers.

**Methods**

Participants and study design

Eligible patients and carers consecutively identified as nearing discharge from the acute stroke unit of two public, tertiary hospitals in Brisbane, Australia were invited to participate in this randomised trial. Eligibility criteria included: (1) having, or being a carer for someone with, a current diagnosis of stroke (first or subsequent) or transient ischaemic attack (TIA); (2) not living in residential care prior to admission to hospital, or having residential care as planned discharge destination; (3) contactable by telephone; and (4) adequate English, cognition and communication, vision and hearing to participate in an interview and complete the questionnaire. If the patient was ineligible, available carers were still approached.

Procedure

Members of the treating multidisciplinary team assisted in identifying eligible participants. The lead author obtained informed, written consent and completed the initial interviews. Concealed, random allocation was achieved via sequentially numbered envelopes containing



computer-generated random numbers prepared by a person not involved in the study. Paired patient and carer dyads were allocated to the same group.

Outcome measures were administered face-to-face prior to acute stroke unit discharge (mean 12.8, SD 9.3 days since stroke). They were re-administered via telephone three months after discharge (mean 112.1, SD 14.1 days since stroke) by a researcher who was blind to group allocation. Once completed, the assessor opened a sealed section of the form to determine group allocation and asked intervention group participants additional questions regarding the intervention. A comparison of telephone and face-to-face administration of these measures found no significant differences between the two methods<sup>20</sup>.

Demographic and clinical characteristics were collected at baseline from participant interview and from patients' medical chart. The Rapid Estimate of Adult Literacy in Medicine (REALM)<sup>21</sup> was also administered at baseline as an estimate of participants' reading ability. The REALM is a reading recognition test with good test-re-test reliability and concurrent validity with standardised reading tests<sup>21</sup>.

Ethical clearance was obtained from relevant hospital and university ethics committees and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTR Number: ACTRN12608000469314).

### Intervention

Control group participants received standard stroke unit care, which included medical, nursing and allied health treatment. Participants in the intervention group received the

education and support package in addition. The package consisted of: a computer-generated, tailored written information booklet ([www.uq.edu.au/tru/strokebook](http://www.uq.edu.au/tru/strokebook))<sup>16</sup>; verbal reinforcement of information up to three times pre-discharge; telephone contact up to three times post-discharge; and a telephone number that participants could call with questions. Participants could tailor the written information by choosing topics from a list of 34 topics and the level of information detail (detailed or brief)<sup>22</sup> and the verbal sessions by nominating the topics for discussion. Intervention group participants received the written information and face-to-face sessions prior to discharge interview. Following discharge, telephone contact to participants was provided by three health-professional-initiated telephone calls approximately monthly, over a three month period. (Further details of the intervention are available from the author on request.

As the intervention also contained information related to secondary stroke prevention and subsequent risk-related behaviour change, development of the intervention according to a validated health behaviour change model was required. The Health Belief Model<sup>23</sup> and adult learning principles<sup>24</sup> were used to inform the development of the intervention. As a result, the health professional providing the intervention incorporated the following strategies where possible: assessing knowledge, exploring barriers and ways to overcome them; correcting misinformation; providing specific and personalised information about the risks and seriousness of unhealthy behaviour, and specific details of the benefits of healthy behaviour; providing reassurance and encouraging the use of support networks; using persuasion and training in breaking tasks into smaller steps; and encouraging the use of stress management strategies.

### Outcome measures

The primary outcome was stroke knowledge and assessed using the Knowledge of Stroke Questionnaire<sup>16</sup> which has a true/false/don't know response format and has good test-retest reliability<sup>25</sup>. Secondary outcomes were self-efficacy, anxiety and depression, quality of life (patients) and caregiver burden (carers) and ratings of: being informed; importance of information; and satisfaction with information received. Due to a lack of a suitable existing measure, a tool for assessing self-efficacy in accessing and using stroke information was developed for this study, drawing on Lorig and colleagues' Self-efficacy to Perform Self-Management Behaviour measures for chronic disease<sup>26</sup>. It consists of nine items, each scoring self-efficacy on a 1-10 Likert scale, and using a stem statement of "At the moment, how confident are you that you...?"

Anxiety and depression was assessed using the 14-item Hospital Anxiety and Depression Scale (HADS)<sup>27</sup> (scores range from 0-21 for each anxiety and depression subscale), with higher scores indicating higher levels of anxiety or depression. Patient-specific quality of life was assessed using the Stroke and Aphasia Quality of Life Scale-39 Generic (SAQOL-39g) which has been validated on patients with and without aphasia<sup>28</sup>. The 39 items, each scored on a Likert scale of 1-5, are organised into three categories: physical, psychosocial and communication. Higher category and total means indicate better quality of life. The carer-specific measure of burden was assessed using the Caregiver Strain Index (CSI), for which scores range from 0-13 with higher total scores indicating higher burden<sup>29</sup>. Self-reported ratings of being informed, the importance of information and satisfaction with information

received were assessed using 10-point Likert scales, where 1 = “not at all...” and 10 = “extremely...”.

Finally, questions were asked of the intervention group participants to obtain feedback on the intervention. These included asking if they had read the booklet, and the usefulness of each of the four components of the intervention on a 1-10 Likert scale, where 1=“not at all useful” and 10=“extremely useful”.

Sample size and statistical analysis

A sample size calculation was conducted for the primary outcome of stroke knowledge based on data from previous research<sup>16</sup> and on the expectation that a between-group difference of a mean score of 2 would be clinically significant. Assuming equality of groups pre-intervention, using a standard deviation of 3.6, power of 0.8 and a significance level of 0.05 (two-sided), a required sample size of 102 (51 in each group) was predicted. To allow for a possible attrition rate of 25%, a target of 136 participants was set. To identify potential underpowering, post-hoc power calculations were conducted for each outcome measure.

Statistical analysis was conducted using STATA (version 10) and on an intention-to-treat basis. Because of baseline differences in age between the groups, ANCOVAs were completed on follow-up scores for all outcomes. Participants included both patients and carers, with data analysed together.

## Results

The flow of participants through the trial is presented in Figure 1. Recruitment occurred over a thirteen month period between 2008 and 2009. Of the 138 participants randomised, 8 control group participants and 11 intervention group participants were lost to follow-up, resulting in an overall follow-up rate of 86%. Demographic and clinical characteristics of participants are presented in Table 1. Just over half of the participants (55.5%) had their paired patient or carer also participating in the study. Baseline and follow-up outcome measure scores are presented in Table 2. Participant mean age at baseline was significantly different between the control and intervention groups (61.8 vs. 55.1 years).

At the three month follow-up, participants in the intervention group had significantly better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with information received relating to medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ) (see Table 2). There were no significant between-group differences for the other outcomes.

### Intervention provision and feedback

The mean number of contacts prior to discharge was 1.3 (SD 0.6, range 1-3) and 2.5 (SD 0.9 range 0-3) following discharge. The mean total minutes of contact prior to discharge was

25.5 (SD 14.9, range 2-60) and following discharge was 8.6 (SD 8.3, range 1-43). The mean length of total contact time (face-to-face and telephone) was 59.1 minutes (SD 40.0, range 9-196). Only one participant (a patient) made use of the telephone support number to contact the health professional with a question. Please see Table 3 which presents the proportion of participants who reported each component of the intervention as useful and the mean usefulness rating. Fifty-five (91.7%) of participants in the intervention group stated that they had read the written booklet.

**Discussion**

The provision of a tailored education and support package resulted in significantly better self-efficacy in accessing stroke information, feelings of being informed, and satisfaction with information received. A strength of this study is its randomised controlled design. Additionally, the inclusion of both patients and carers enhances the applicability to health professionals working in this clinical area. One limitation of this study is that these results may not be generalisable to patients with more severe cognitive impairment or aphasia or to patients who require high-level residential care and their carers. These populations are commonly excluded from studies of educational interventions and identifying effective educational resources, as well as methods by which to conduct this research are current research gaps. Post hoc power analysis indicated that the primary and several of the secondary outcome measures used in this trial were underpowered and the possibility of a Type II error should also be considered. Finally, a three month follow-up period may also not have been sufficient to see the full influence of the intervention.

Our study used a 25-item stroke knowledge test, which allowed comparison with the previous RCT of the tailored written booklet used as part of the current study's intervention<sup>16</sup>.

Hoffmann and colleagues found a non-significant between-group difference of 0.1<sup>16</sup>, while for this study it was 0.9, yet also non-significant. A more sensitive outcome measure or variations to the intervention (such as greater intensity) may be required to observe a significant between-group difference in stroke knowledge.

Insufficient intensity of the intervention may have also contributed to the lack of significant differences between the groups for the other outcomes, along with underpowering of the study. Although a total up to six contacts with the health professional were offered, some participants declined some of these. This may have diluted the effect of the intervention.

Possible explanations for the amount of post-discharge contact being considerably less than the amount of pre-discharge contact include: difficulty engaging some participants in discussion over the telephone; or needs other than information taking a higher priority once a patient has left the acute ward. Additionally, although care was taken to ensure the telephone contacts occurred at times suitable to the participant, participants may have felt that they did not have 'time to talk' or were not as prepared for the discussion as they could have been.

This emphasises the need to complete a regular, formal review of information needs<sup>18, 30</sup>.

Formalising the information provision by scheduling an outpatient appointment may overcome some barriers of telephone communication, but may create other difficulties for patients and carers. The use of alternative communications such as Skype or video-conferencing may be more resource- and time-efficient, and more convenient for patients and/or carers who experience difficulties with community mobility and transport post-stroke. Alternative solutions should be explored, depending on the resources and infrastructure available to stroke patients, their carers, and the health facility in which the health

professionals work. Information needs persist and change beyond hospital discharge<sup>4,31</sup> and health professionals need to find ways to continually meet these changing needs.

In the current study participants in the intervention group had significantly better self-efficacy for accessing stroke information. Several health education theories describe self-efficacy as an important precursor to performance of a task<sup>23</sup>. This has important implications for the abilities of patients with stroke and their carers to meet ongoing information needs, as it suggests that the intervention may empower them to independently access stroke information even after the intervention period ceased. Facilitating self-efficacy has been found to improve longer-term health outcomes in patients with chronic health conditions<sup>32</sup>.

In the current study participants in the intervention group also demonstrated better satisfaction than control group participants. Higher satisfaction was also found by Hoffmann et al<sup>16</sup>. However the current study did not find a significant improvement in knowledge in the intervention group which had been found by Lowe et al<sup>15</sup>. The content of Lowe's booklets contained both general and patient-specific stroke information, while the content of our booklets was entirely tailored by the participants' choice of content and level of information. This more complete tailoring may make it difficult to accurately assess the knowledge of all participants using a uniform measure as not all participants will have been exposed to the same content. Perhaps a knowledge outcome measure that is more sensitive to differing content exposure is required to detect differences achieved from a tailored intervention.

The intervention group participants rated all four intervention components highly, including the post-discharge options of talking to someone over the telephone and having a telephone support person available if needed. A Cochrane review of health professional-initiated



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3 telephone contact with patients following hospital discharge concluded that the effect of this  
4 medium on patient outcomes is currently inconclusive<sup>33</sup>. While this review included studies  
5 which involved patients from various diagnostic groups, it did not include any studies  
6 specifically with stroke patients. The needs of stroke patients and their carers post-discharge  
7 can differ quite substantially to those of other patient groups and stroke-specific studies  
8 evaluating this are needed. Stroke patients and carers have reported satisfaction with  
9 receiving telephone support when provided in combination with face-to-face provision<sup>34</sup> and  
10 a desire to receive telephone support as a follow-up to face-to-face provision<sup>35</sup>.  
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22 The high ranking of the usefulness of having someone to call with questions was surprising  
23 given that this option was utilised by only one participant. It may be that participants did not  
24 use this option because the health professional who provided the intervention appropriately  
25 elicited and addressed information needs during the health professional-initiated contacts, or  
26 that intervention group participants accessed other sources of information to ask additional  
27 questions. Nevertheless, it appears that participants in this study were satisfied to know that  
28 there was someone to call, even if they did not utilise the service. The need to provide contact  
29 details for any questions that may arise following discharge is acknowledged in national and  
30 international stroke care guidelines<sup>1-3</sup>. Appropriate post-discharge support and/or contact is  
31 often identified as a gap in services, by both patients and carers<sup>8</sup> and hospitals which provide  
32 stroke care<sup>36</sup>.  
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#### 50 Areas for future research

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52 A qualitative component of this study may have enhanced interpretation of the quantitative  
53 results and provided further insights into participants' perspectives about components of the  
54 intervention. Outcome measures relating to self-efficacy, satisfaction and ratings of the  
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importance of information and feeling informed were developed for this study due to a lack of existing measures and exploration of their psychometric properties, sensitivity to change, and their suitability for people with aphasia would be valuable.

Enhancement of the intervention may be needed to influence psychosocial outcomes. This enhancement may come from combining its provision with other active informational interventions. For example, hands-on practical training for carers has been demonstrated to reduce in patient anxiety and depression and carer anxiety, depression and burden<sup>37</sup>. A recent systematic review of educational needs of patients with stroke and their carers calls for improvements in stroke education<sup>4</sup>. Enhancement and provision of this tailored stroke information package may be one way of addressing this need.

**Conclusion**

The provision of a tailored education and support package resulted in significantly better self-efficacy in accessing stroke information, feelings of being informed, and satisfaction with information received. Further enhancement of the package and evaluation of its effect on other health outcomes is required. Tailored stroke information should be an essential component of post-stroke care.

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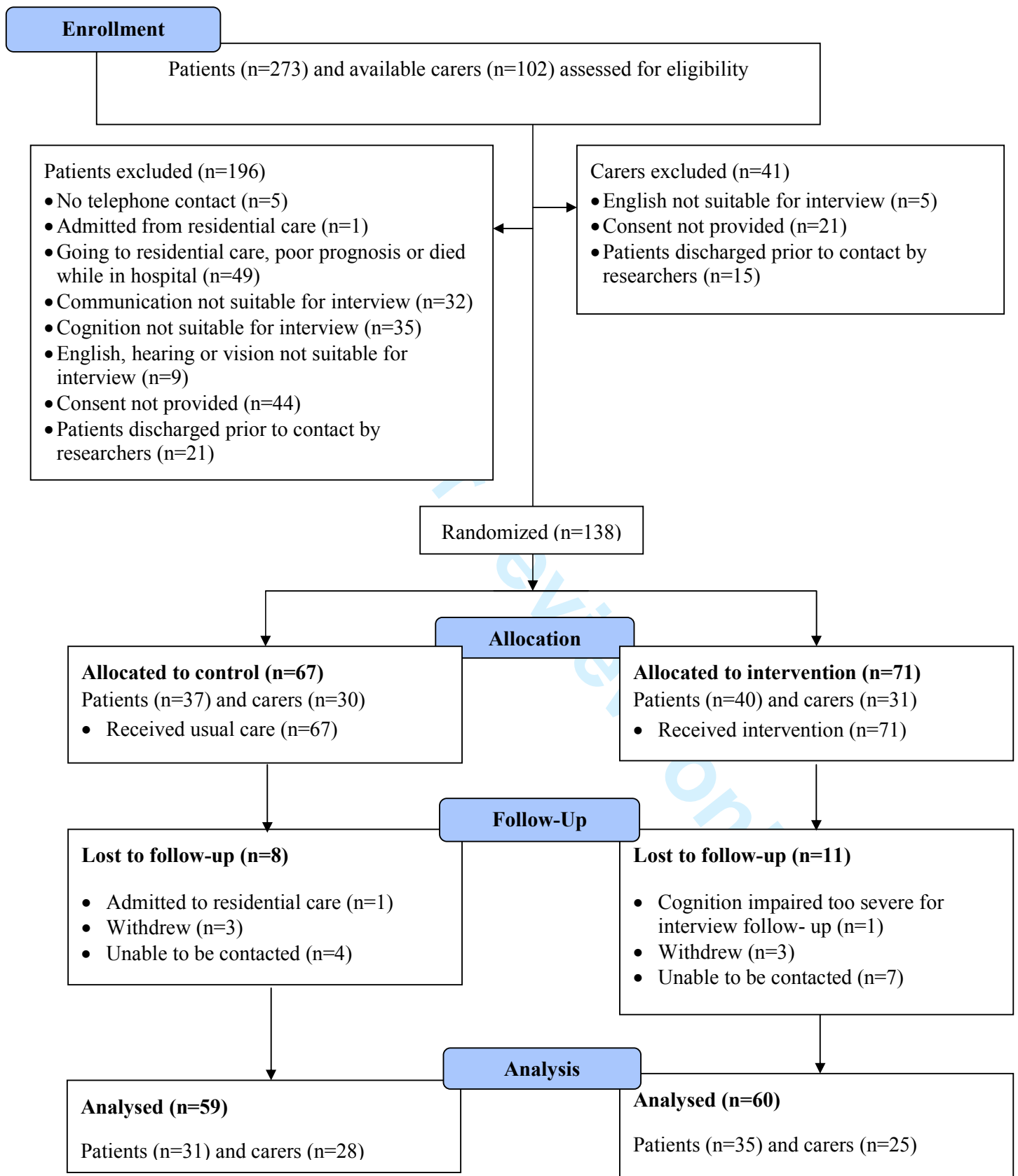
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**Figure 1:** Flow of participants

**Table 1:** Demographic and clinical characteristics at baseline. Values are numbers (percentages) unless otherwise stated

Variable	Control (n=67)	Intervention (n=71)
Mean age in years (SD; range)	61.4 (12.7; 24-86)	55.2 (16.7; 27-97)
Female gender	36 (53.7)	39 (54.9)
Living with:		
Alone	10 (14.9 )	13 (18.3)
Partner / family	57 (85.1)	58 (81.7)
Relationship to patient <sup>a</sup>	(n=30)	(n=31)
Partner	21 (70.0)	20 (64.5)
Child	7 (23.3)	9 (29.0)
Sibling/other	2 (6.7)	2 (6.5)
Mean years of schooling (SD; range)	11.8 (3.6; 2-21)	12.1 (3.3; 6-20)
REALM grade equivalent: <sup>b</sup>	(n=62)	(n=67)
≤ 3rd	0	1 (1.5%)
4 <sup>th</sup> -6 <sup>th</sup>	3 (4.8)	3 (4.5)
7 <sup>th</sup> -8 <sup>th</sup>	19 (30.6)	19 (28.4)
≥9 <sup>th</sup>	40 (64.5)	44 (65.7)



**Table 1 continued:** Demographic and clinical characteristics at baseline

Patient stroke type: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Ischaemic	31 (86.1)	29 (72.5)
Haemorrhagic	5 (13.9)	10 (25)
TIA	0	1 (2.5)
Patient side of stroke: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Left	12 (33.3)	15 (37.5)
Right	21 (58.3)	24 (60.0)
Bilateral	3 (8.3)	1 (2.5)
First-time stroke <sup>c</sup>	(n=37)	(n=40)
	31 (83.8)	27 (67.5)

<sup>a</sup> Carer participants only

<sup>b</sup> Eight patients and one carer were unable to complete the REALM due to poor vision

<sup>c</sup> Patient participants only

<sup>d</sup> One patient's stroke type and side was missing

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**Table 2:** Baseline and 3 month follow-up outcome measures scores

Outcome (score range)	Mean (SD) baseline scores		Mean (SD) follow-up scores		ANCOVA results		
	Control	Intervention	Control	Intervention	Between group	p-value	Post hoc
	group	group	group	group (n=60)	difference		power
	(n=59)	(n=60)	(n=59)		adjusted mean (95% CI)		calculation  f-value
Stroke knowledge (0-25)	17.2 (3.9)	17.5 (3.1)	18.7 (3.5)	19.8 (3.0)	0.9 (-0.4 to 2.2)	0.176	0.11^
Self-efficacy (1-10)							
Cope with stroke	6.8 (2.6)	7.1 (2.3)	7.7 (1.9)	8.1 (1.8)	0.2 (-0.5 to 0.8)	0.600	0.05^
Access practical help	7.8 (2.3)	8.2 (2.0)	8.3 (1.9)	8.5 (1.5)	0.2 (-0.4 to 0.9)	0.483	0.07^
Access emotional help	7.8 (2.4)	8.0 (2.1)	8.1 (2.0)	8.0 (2.1)	0.0 (-0.7 to 0.9)	0.909	0.01^
Manage stress	7.2 (2.3)	7.5 (2.2)	7.3 (2.1)	7.6 (1.7)	0.2 (-0.5 to 0.9)	0.584	0.05^

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores**Self-efficacy (1-10)** continued

Access stroke information	7.6 (2.5)	7.8 (2.4)	7.8 (2.2)	8.8 (1.4)	1.0 (0.3 to 1.7)	0.004*	0.28
Understand stroke information	7.9 (1.9)	7.9 (2.1)	7.9 (1.9)	8.5 (1.4)	0.6 (-0.1 to 1.2)	0.077	0.17^
Talk with doctor	8.6 (2.0)	8.9 (1.4)	8.7 (1.5)	8.9 (1.7)	0.1 (-0.5 to 0.8)	0.651	0.04^
Talk with health professionals	8.5 (1.8)	8.7 (1.8)	8.6 (1.6)	8.7 (1.6)	0.2 (-0.4 to 0.8)	0.567	0.05^
Prevent (another) stroke	7.0 (2.4)	6.9 (2.7)	6.8 (2.2)	7.3 (2.7)	0.2 (-0.7 to 1.2)	0.608	0.05^
<b>Anxiety (0-21)</b>	7.5 (4.2)	8.7 (4.5)	6.6 (4.3)	7.3 (4.3)	0.5 (-1.1 to 2.1)	0.559	0.05^
<b>Depression (0-21)</b>	5.0 (3.4)	5.4 (3.8)	4.3 (3.5)	4.9 (3.6)	0.6 (-0.7 to 2.0)	0.377	0.08^
<b>Feeling informed (1-10)</b>	6.1 (2.6)	6.0 (2.3)	7.3 (1.9)	8.2 (1.7)	0.9 (0.2 to 1.6)	0.008*	0.25
<b>Importance of information (1-10)</b>	9.9 (0.4)	9.6 (1.2)	9.4 (1.4)	9.5 (1.1)	0.1 (-0.4 to 0.6)	0.615	0.05^

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**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

<b>Satisfaction with information received (1-10)</b>							
Medical information	6.3 (2.5)	6.5 (2.3)	6.8 (2.6)	8.8 (1.8)	2.0 (1.1 to 2.8)	<0.001*	0.43
Practical information	5.9 (2.7)	6.2 (2.7)	7.4 (2.5)	8.5 (1.9)	1.1 (0.3 to 1.9)	0.008*	0.25
Service and benefits	5.3 (3.0)	5.8 (2.8)	7.1 (2.7)	7.9 (1.8)	0.9 (0.1 to 1.8)	0.036*	0.20
Prevention information	5.8 (2.7)	6.2 (2.7)	6.9 (2.6)	8.6 (1.7)	1.7 (0.9 to 2.5)	<0.001*	0.39
<b>Quality of life (patients) (1-5)</b>	(n=31)	(n=35)	(n=31)	(n=35)	0.1 (-0.2 to 0.4)	0.496	0.09^
	3.5 (0.8)	3.6 (0.8)	4.1 (0.7)	4.0 (0.7)			
<b>Caregiver burden (carers) (0-13)</b>	(n=28)	(n=25)	(n=28)	(n=25)	0.1 (-2.0 to 2.1)	0.932	0.01^
	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)			
* significant difference between groups      ^ f-value indicated underpowering likely							

**Table 3:** Satisfaction with intervention components

Intervention component	Participant reported component as useful n (%) (n=60 )	Mean (SD) usefulness rating (1-10)
Written component	53 (88.3)	9.1 (1.4)
Talking to someone face-to-face (in hospital)	58 (96.7)	8.9 (1.6)
Talking to someone over the telephone (following discharge)	45 (75.0)	7.9 (2.3)
Having a telephone support person available if needed	51 (85.0)	8.2 (2.4)

**Authors' contribution**

Dr Eames was partially responsible for concept design, and primarily responsible for review of the literature, participant recruitment, data collection, data analysis and interpretation and manuscript preparation. Ass Prof. Hoffmann and Prof. Worrall were partially responsible for concept design and also provided peer-review of data analysis and interpretation and manuscript preparation. Dr Read and Dr Wong provided peer-review of data interpretation and manuscript preparation.

**Funding statement**

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**Data sharing statement**

The dataset is available at Dryad repository (provisional doi:10.5061/dryad.hs03q), who will provide a permanent, citable and open access home for the dataset.



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6-7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6-7,
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7

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3		11b	If relevant, description of the similarity of interventions	7
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
6				
7	<b>Results</b>			
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
9	diagram is strongly		were analysed for the primary outcome	
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	11 & 21
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
12		14b	Why the trial ended or was stopped	N/A
13				
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	21-22
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	21
16			by original assigned groups	
17				
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	24-26
19	estimation		precision (such as 95% confidence interval)	
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	N/A
22			pre-specified from exploratory	
23				
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
25				
26	<b>Discussion</b>			
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-16
30				
31	<b>Other information</b>			
32	Registration	23	Registration number and name of trial registry	2 & 7
33	Protocol	24	Where the full trial protocol can be accessed, if available	N/A
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	28
35				

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37 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

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### Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of the study as randomized	1
Authors *	Contact details for the corresponding author	Separate attachment
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	1
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	1
Interventions	Interventions intended for each group	1
Objective	Specific objective or hypothesis	1
Outcome	Clearly defined primary outcome for this report	1-2
Randomization	How participants were allocated to interventions	1
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	1
Results		
Numbers randomized	Number of participants randomized to each group	1
Recruitment	Trial status	1
Numbers analysed	Number of participants analysed in each group	1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	2
Harms	Important adverse events or side effects	N/A
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	2
Funding	Source of funding	End of article

*\*this item is specific to conference abstracts*

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-Please complete option 1 or 2 as appropriate and sign below. If you answered "yes" to any of the 5 questions relating to financial competing interests (or you wish to disclose a non-financial competing interest), you should write a statement below.

Sally Eames    ☐ None declared    Please insert the following statement under competing interests

Tammy Hoffmann    ☐ None declared    ☐ Please insert the following statement under competing interests

TH receives income from subscription fees to the tailored stroke education package which enable technical maintenance of the website and database.

Linda Worrall    ☐ None declared    Please insert the following statement under competing interests

Stephen Read    ☐ None declared    Please insert the following statement under competing interests

Andrew Wong    ☐ None declared    Please insert the following statement under competing interests

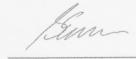
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Title of paper: Randomised controlled trial of an education and support package for stroke patients and their carers

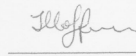
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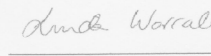
(Print name)



Sally Eames



Tammy Hoffmann



Linda Worrall

(Please see attached)

Stephen Read

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Title of paper: Randomised controlled trial of an education and support package for stroke patients and their carers

Date:

Signature (all authors to sign):	(Print name)
_____	Sally Eames
_____	Tammy Hoffmann
_____	Linda Worrall
_____  _____	Stephen Read
_____	Andrew Wong

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*(Print name)*

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## Randomised controlled trial of an education and support package for stroke patients and their carers

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002538.R1
Article Type:	Research
Date Submitted by the Author:	26-Feb-2013
Complete List of Authors:	Eames, Sally; Brighton Health Campus & Services, Hoffmann, Tammy Worrall, Linda Read, Stephen Wong, Andrew
<b>Primary Subject Heading</b>:	Neurology
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Stroke < NEUROLOGY, EDUCATION & TRAINING (see Medical Education & Training), REHABILITATION MEDICINE

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Manuscripts

**Randomised controlled trial of an education and support package for stroke patients and their carers**

**Abstract**

**Objective:**

Tailoring stroke information and providing reinforcement opportunities are two strategies proposed to enhance the effectiveness of education. This study aimed to evaluate the effects of an education package which utilised both strategies on the knowledge, health and psychosocial outcomes of stroke patients and carers.

**Design:**

Multi-site, randomised trial comparing usual care with an education and support package

**Setting:**

Two acute stroke units.

**Participants:**

Patients and their carers (N=138) were randomised (control n=67, intervention n=71) of which data for 119 participants (control n=59, intervention n=60) were analysed.

**Intervention:**

The package consisted of a computer-generated, tailored written information booklet and verbal reinforcement provided prior to, and for three months following, discharge.

**Outcome measures:**

Outcome measures were administered prior to hospital discharge and at three month follow-up by blinded assessors. The primary outcome was stroke knowledge (score range: 0-25). Secondary outcomes were: self-efficacy (1-10), anxiety and depression (0-21), ratings of importance of information (1-10), feelings of being informed (score range: 1-10), satisfaction with information (1-10), caregiver burden (carers) (0-13) and quality of life (patients) (1-5).

### Results:

Intervention group participants reported better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention information (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ). There was no significant effect on other outcomes.

### Conclusions:

Intervention group participants had improved self efficacy for accessing stroke information and satisfaction with information, but other outcomes were not significantly affected. Evaluation of a more intensive intervention in a trial with a larger sample size is required to establish the value of an educational intervention that uses tailoring and reinforcement strategies.

ACTRN12608000469314



**Article summary**

**Article focus:**

- Patient and carer education is a crucial component of post-stroke care but little is known about the most effective way of providing it.
- Tailoring stroke information and providing opportunities for reinforcement have been suggested as useful strategies.
- This study aimed to evaluate the effects of an education package which used both of these strategies on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers.

**Key messages**

- The education and support package included a computer-generated, tailored written information booklet and verbal reinforcement and commenced in hospital and continued during the three months following discharge,.
- The package improved stroke self-efficacy for accessing stroke information and satisfaction with information received.
- The effects of tailored messages and verbal reinforcement on other outcomes, such as knowledge, mood, quality of life/caregiver burden, remains unknown.

**Strengths and limitations of this study**

- This intervention evaluated in this study was theoretically informed, developed with patient and carer input, and expanded on a previous trial. The inclusion of both patients and carers enhances the applicability to clinicians working in this area as patients are often seen with their carers or a family member.

- Results may not be generalisable to all patients with stroke. The sample size was small and the study likely to be underpowered. Some of the outcome measures lack formal evaluation of psychometric properties.

For peer review only

**Introduction**

Stroke information provision is a crucial component of care for patients and carers <sup>1-3</sup>, however their information needs are often poorly met. <sup>4-8</sup> Information needs vary between individuals <sup>9</sup> and tailoring of information to individual patient and/or carer needs is required. <sup>10-13</sup>

Three tailored written information interventions for patients with stroke have been evaluated in randomised trials. <sup>14-16</sup> In an evaluation of booklets that contained information previously presented verbally there were no significant differences in physical or social functioning between groups. <sup>14</sup> Evaluation of individualised information booklets that were verbally reinforced in one session found significantly better stroke knowledge for intervention group patients, but no other between-group differences. <sup>15</sup> In a trial which compared a computer-generated tailored written information booklet (‘What you need to know about stroke’) with generic non-tailored stroke information, intervention group patients had significantly better satisfaction with information received and their information needs were better met, but no other significant improvements compared to the control group. <sup>16</sup> These studies suggest that while there may be some benefits associated with tailored written information, refinement of tailored stroke educational interventions and further research is required.

A possible mechanism for enhancing the effectiveness of stroke information interventions is suggested in a Cochrane review, in which ‘active’ interventions (which actively included patients and carers and provided the opportunity to clarify and reinforce information) were found to be more effective at improving patient anxiety and depression than passive ones. <sup>17</sup> Furthermore, because patients and carers continue to have information needs after leaving hospital, <sup>4, 8, 18</sup> continued access to information after discharge is recommended. <sup>1</sup>

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5 In the current study, an education and support package for patients and carers that expanded  
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7 upon the previously evaluated 'What you need to know about stroke' tailored booklet and  
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9 provided opportunities for clarification and reinforcement of information both prior to, and  
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11 following, discharge, was developed. Research into patients' and carer's information needs  
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13 and format preferences<sup>19</sup> was also used to inform the intervention design, as was the Health  
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15 Belief Model<sup>20</sup> and adult learning principles. The Health Belief Model has previously been  
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17 used in the area of stroke as a basis to explore patient beliefs regarding risk-related behaviour  
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19 change.<sup>21</sup> The model assumes that in order for behaviour change to occur, a person must  
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21 believe: that they are at risk of a particular illness (perceived susceptibility); that the  
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23 consequence of that illness is serious (perceived severity); that making the behaviour change  
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25 can produce a positive outcome (perceived benefit); and that the perceived benefit of  
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27 behaviour change outweighs any perceived barriers to behaviour change.<sup>20</sup> Another  
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29 component of the model is the person's self-efficacy (confidence in their ability) to perform a  
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31 behaviour.<sup>20</sup> As the intervention was targeted at adults, the principles of adult learning were  
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33 also incorporated in the education package.<sup>22</sup> These principles include consideration of a  
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35 person's: need to know, self concept, prior experiences, readiness to learn, orientation to  
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37 learning, and motivation to learn.<sup>22</sup>  
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45 The research question addressed by this study was "What are the effects of an education and  
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47 support package on the knowledge, health, psychosocial and satisfaction outcomes of stroke  
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49 patients and carers?" The primary aim of this study was to evaluate the effect of this  
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51 education package on the knowledge of stroke patients and carers; with a secondary aim of  
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53 evaluating its effect on participants' self-efficacy, mood, feelings of being informed and the  
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55 importance of information, satisfaction, and patient quality of life / carer burden.  
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**Methods**

Participants and study design

Eligible patients consecutively identified as nearing discharge from the acute stroke unit of two public, tertiary hospitals in Brisbane, Australia and their carers were invited to participate in this randomised trial. Eligibility criteria included: (1) having, or being a carer for someone with, a current diagnosis of stroke (first or subsequent) or transient ischaemic attack (TIA); (2) not living in residential care prior to admission to hospital, or having residential care as planned discharge destination; (3) contactable by telephone; and (4) adequate English, cognition and communication, vision and hearing to participate in an interview and complete the questionnaire. Members of the treating interdisciplinary team assisted in identifying eligible patients, and available and eligible carers. For example, the treating speech pathologist advised on patients' communication ability, and the treating doctor or occupational therapist advised on patients' cognitive ability. If the patient was ineligible, available carers were still approached.

Procedure

The lead author obtained informed, written consent and completed the initial interviews. Concealed, random allocation was achieved via sequentially numbered envelopes containing computer-generated random numbers prepared by a person not involved in the study. Paired patient and carer dyads were allocated to the same group. Participants then received standard care (control group) or standard care and the intervention (intervention group) until three months following discharge.

Outcome measures were administered face-to-face prior to acute stroke unit discharge (mean 12.8, SD 9.3 days since stroke). They were re-administered via telephone three months after discharge (mean 112.1, SD 14.1 days since stroke) by a different researcher who was blind to group allocation. Once completed, this assessor opened a sealed section of the form to determine group allocation and asked intervention group participants additional questions regarding the intervention. A comparison of telephone and face-to-face administration of these measures found no significant differences between the two methods.<sup>23</sup>

Demographic and clinical characteristics were collected at baseline from participant interview and from patients' medical chart. The Rapid Estimate of Adult Literacy in Medicine (REALM)<sup>24</sup> was also administered at baseline as an estimate of participants' reading ability. The REALM is a reading recognition test with good test-re-test reliability and concurrent validity with standardised reading tests.<sup>24</sup> Ethical clearance was obtained from relevant hospital and university ethics committees and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTR Number: ACTRN12608000469314).

### Intervention

Control group participants received standard stroke unit care (medical, nursing and allied health assessment and treatment, which included the provision of unstructured informal verbal education and advice from various members of the treating team) No structured stroke education or support groups were offered at either site during the time of this study nor were written materials routinely provided. Participants in the intervention group received the education and support package in addition to standard care.

The design of the education and support package was informed by recommendations from the literature,<sup>25</sup> and previous research by the author team which explored current practice gaps,<sup>25</sup> patient and carer preferences for receiving information<sup>19</sup> and potential barriers to information provision.<sup>26</sup> The health professional providing the package was the lead author, who is an occupational therapist with clinical experience in stroke rehabilitation, however the intervention was designed so that it could be provided by any health professional who has knowledge and experience in stroke management.

The package consisted of: a previously evaluated and described computer-generated, tailored written information booklet ([www.uq.edu.au/tru/strokebook](http://www.uq.edu.au/tru/strokebook));<sup>16, 27</sup> verbal reinforcement of information up to three times pre-discharge; telephone contact up to three times post-discharge; and a telephone number that participants could call with questions. Participants could tailor the written information by choosing topics from a list of 34 topics and the level of information detail (detailed or brief)<sup>27</sup> (please see online supplementary materials) and the verbal sessions by nominating the topics for discussion. Intervention group participants received the written information and face-to-face sessions prior to discharge interview (please see online supplementary materials). Following discharge, telephone contact to participants was provided by three health professional-initiated telephone calls at intervals of approximately one month, over a three month period (please see inline supplementary materials). As the Health Belief Model<sup>20</sup> and adult learning principles<sup>22</sup> was used to inform the development of the intervention, the health professional providing the intervention incorporated the following strategies where possible: assessing knowledge, exploring barriers and ways to overcome them; correcting misinformation; providing specific and personalised information about the risks and seriousness of unhealthy behaviour, and specific details of the benefits of healthy behaviour; providing reassurance and encouraging the use of support

networks; using persuasion and training in breaking tasks into smaller steps; and encouraging the use of stress management strategies.

The health professional providing the intervention was not a member of the interdisciplinary team at either stroke unit and approached participants independent of the standard treating team. Face-to-face sessions were conducted at the patients' bedside or in a nearby quiet interview room. In the case of participating dyads (both patient and their carer allocated to the intervention group), participants were offered the choice of combined or separate education sessions. The information needs checklist, intervention protocol and the intervention tracking template are provided as online supplementary materials. Further details of the intervention are available from the author on request.

### Outcome measures

The primary outcome was stroke knowledge and assessed using the 25-item Knowledge of Stroke Questionnaire<sup>16</sup> which has a true/false/don't know response format and has good test-retest reliability,<sup>28</sup> with higher scores indicating better stroke knowledge. Secondary outcomes were self-efficacy, anxiety and depression, quality of life (patients) and caregiver burden (carers) and ratings of: being informed; importance of information; and satisfaction with information received. Due to a lack of a suitable existing measure, the tool for assessing self-efficacy in accessing and using stroke information that was developed for this study, drawing on Lorig and colleagues' Self-efficacy to Perform Self-Management Behaviour measures for chronic disease.<sup>29</sup> It consists of nine items (see Table 2), each scoring self-efficacy on a 1-10 Likert scale, and using a stem statement of "At the moment, how confident are you that you...?"



Anxiety and depression was assessed using the 14-item Hospital Anxiety and Depression Scale (HADS) <sup>30</sup> (scores range from 0-21 for each anxiety and depression subscale), with higher scores indicating higher levels of anxiety or depression. The internal consistency, as indicated by Spearman's correlation, of the HAD's anxiety subscale items has been reported as ranging from +0.76 to +0.41 ( $p < 0.01$  for all items) and for the depression subscale, +0.60 to +0.30 (all lower than  $p < 0.02$ ). <sup>30</sup> Self-reported ratings of being informed, the importance of information and satisfaction with information received were assessed using 10-point Likert scales, where 1 = "not at all..." and 10 = "extremely..."

Finally, patient-specific quality of life was assessed using the Stroke and Aphasia Quality of Life Scale-39 Generic (SAQOL-39g) which has been validated on patients with and without aphasia. <sup>31</sup> The 39 items, each scored on a Likert scale of 1-5, are organised into three categories: physical, psychosocial and communication. Higher category and total means indicate better quality of life. The SAQOL-39 has acceptable test-retest reliability (intraclass correlation coefficient = 0.89 to 0.98), internal consistency (Cronbach's  $\alpha = 0.74$  to 0.94), and construct validity (corrected domain-total correlations,  $r = 0.38$  to 0.58; convergent,  $r = 0.55$  to 0.67; discriminant,  $r = 0.02$  to 0.27 validity)". <sup>32</sup> A carer-specific measure of burden was assessed using the Caregiver Strain Index (CSI), for which scores range from 0-13 with higher total scores indicating higher burden. <sup>33</sup> It has strong internal consistency (Cronbach's  $\alpha = 0.86$ ), <sup>33</sup> clinical validity and significant correlation with other caregiver burden scales. <sup>34</sup>

Finally, questions were asked of the intervention group participants to obtain feedback on the intervention. These included asking if they had read the booklet, and the usefulness of each of

the four components of the intervention on a 1-10 Likert scale, where 1="not at all useful" and 10="extremely useful".

### Sample size and statistical analysis

A sample size calculation was conducted for the primary outcome of stroke knowledge based on data from previous research<sup>16</sup> and on the expectation that a between-group difference of a mean score of 2 would be clinically significant. Assuming equality of groups pre-intervention, using a standard deviation of 3.6, power of 0.8 and a significance level of 0.05 (two-sided), a required sample size of 102 (51 in each group) was predicted. To allow for a possible attrition rate of 25%, a target of 136 participants was set. Statistical analysis was conducted using STATA (version 10) and on an intention-to-treat basis. Because of baseline differences in age between the groups, ANCOVAs were completed on follow-up scores for all outcomes. Participants included both patients and carers, with data analysed together.

### **Results**

The flow of participants through the trial is presented in Figure 1. Recruitment occurred over a thirteen month period between 2008 and 2009, during which time 273 patients and 102 available carers were assessed for eligibility. Of the 138 participants randomised, 8 control group participants and 11 intervention group participants were lost to follow-up, resulting in an overall follow-up rate of 86%. Demographic and clinical characteristics of participants are presented in Table 1. Just over half of the participants (55.5%) had their paired patient or carer also participating in the study. Baseline and follow-up outcome measure scores are

presented in Table 2. Participant mean age at baseline was significantly different between the control and intervention groups (61.8 vs. 55.1years).

At the three month follow-up, there were no significant between-group differences for stroke knowledge. Participants in the intervention group did however, have significantly better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with information received relating to medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ) (see Table 2). There were no significant between-group differences for the other outcomes.

Intervention provision and feedback

The mean number of contacts prior to discharge was 1.3 (SD 0.6, range 1-3) and 2.5 (SD 0.9 range 0-3) following discharge. The mean total minutes of contact prior to discharge was 25.5 (SD 14.9, range 2-60) and following discharge was 8.6 (SD 8.3, range 1-43). The mean length of total contact time (face-to-face and telephone) was 59.1 minutes (SD 40.0, range 9-196). Only one participant (a patient) made use of the telephone support number to contact the health professional with a question. Please see Table 3 which presents the proportion of participants who reported each component of the intervention as useful and the mean usefulness rating. Fifty-five (91.7%) of participants in the intervention group stated that they had read the written booklet.

## Discussion

The provision of a tailored education and support package to stroke patients and carers resulted in participants reporting significantly higher self-efficacy for accessing stroke information, feelings of being informed, and satisfaction with information received. Strengths of this study include: its randomised controlled design; an intervention whose design was informed by a series of previous studies with the intended population; and the inclusion of both patients and carers which enhances the applicability to health professionals working in this clinical area. It is noted that this combined analysis does not allow separation of patient and carer outcomes, which may be of interest to clinicians and researchers. Both patients and carers were recruited as participants for this study as the intervention was designed to meet the needs of both patients and carers and this also allowed maximization of the power of the study.

A limitation of this study is that these results may not be generalisable to patients with more severe cognitive impairment or aphasia or to patients who require high-level residential care and their carers. These populations are commonly excluded from studies of educational interventions and identifying effective educational resources, as well as methods by which to conduct this research are current research gaps. Under powering and the possibility of a Type II error should also be considered. Finally, a three month follow-up period may also not have been sufficient to see the full influence of the intervention.

Our study used a 25-item stroke knowledge test, which allowed comparison with the previous RCT of the tailored written booklet used as part of the current study's intervention.<sup>16</sup> Hoffmann and colleagues found a non-significant between-group difference of 0.1,<sup>16</sup> while for this study it was 0.9, yet also non-significant.. A significant improvement in knowledge in the intervention group had been found by Lowe et al.<sup>15</sup> The content of Lowe's booklets contained both general and patient-specific stroke information, while the content of our booklets was entirely tailored by the participants' choice of content and level of information. This more complete tailoring may make it difficult to accurately assess the knowledge of all participants using a uniform measure as not all participants will have been exposed to the same content. Use of a knowledge outcome measure that is more sensitive to differing content exposure or variations to the intervention (such as greater intensity) may be required to detect differences achieved from a tailored intervention.

Insufficient intensity of the intervention may have also contributed to the lack of significant differences between the groups for the other outcomes, along with underpowering of the study. Although a total of up to six contacts with the health professional providing the intervention were offered, some participants declined some of these. This may have diluted the effect of the intervention. Possible explanations for the amount of post-discharge contact being considerably less than the amount of pre-discharge contact include: reduced tolerance for long telephone conversations due to stroke-or carer-related fatigue; difficulty engaging some participants in discussion over the telephone; or needs other than information taking a higher priority once a patient has left the acute ward. Additionally, although care was taken to ensure the telephone contacts occurred at times suitable to the participant, participants may have felt that they did not have 'time to talk' or were not as prepared for the discussion as they could have been. This emphasises the need to complete a regular, formal review of

information needs.<sup>18, 35</sup> Formalising the information provision by scheduling an outpatient appointment may overcome some barriers of telephone communication, but may create other difficulties for patients and carers such as community mobility. The use of alternative communications such as computer-based video-conferencing may be more resource- and time-efficient, and more convenient for patients and/or carers who experience difficulties with community mobility and transport post-stroke. Alternative solutions should be explored, depending on the resources and infrastructure available to stroke patients, their carers, and the health facility in which the health professionals work. Information needs persist and change beyond hospital discharge<sup>4, 36</sup> and health professionals need to find ways to continually meet these changing needs.

In the current study participants in the intervention group had significantly better self-efficacy for accessing stroke information. Several components of the intervention may have directly contributed to this, including: the written information booklet contained a detailed 'Where to get help' section, and the health professional providing the intervention modelled strategies which encouraged the use of support networks and explored barriers to accessing them and ways overcome these. Several health education theories describe self-efficacy as an important precursor to performance of a task.<sup>20</sup> This has important implications for the abilities of patients with stroke and their carers to meet ongoing information needs, as it suggests that the intervention may empower them to independently access stroke information even after the intervention period ceased. Facilitating self-efficacy has been found to improve longer-term health outcomes in patients with chronic health conditions.<sup>37</sup>

In the current study participants in the intervention group also demonstrated better satisfaction than control group participants. Higher satisfaction was also found by Hoffmann et al.<sup>16</sup> The

intervention group participants rated all four intervention components highly, including the post-discharge options of talking to someone over the telephone and having a telephone support person available if needed. A Cochrane review of health professional-initiated telephone contact with patients following hospital discharge concluded that the effect of this medium on patient outcomes is currently inconclusive.<sup>38</sup> While this review included studies which involved patients from various diagnostic groups, it did not include any studies specifically with stroke patients. The needs of stroke patients and their carers post-discharge differ quite substantially to those of other patient groups and stroke-specific studies evaluating this are needed. Stroke patients and carers have reported satisfaction with receiving telephone support when provided in combination with face-to-face provision<sup>39</sup> and a desire to receive telephone support as a follow-up to face-to-face provision.<sup>40</sup>

The high ranking of the usefulness of having someone to call with questions was surprising given that this option was utilised by only one participant. It may be that participants did not use this option because the health professional who provided the intervention appropriately elicited and addressed information needs during the health professional-initiated contacts, or that intervention group participants accessed other sources of information to ask additional questions. Nevertheless, it appears that participants in this study were satisfied to know that there was someone to call, even if they did not utilise the service. Whether this ‘call in’ component of the intervention would have been better utilised had the follow-up period been longer is also unknown. The need to provide contact details for any questions that may arise following discharge is acknowledged in national and international stroke care guidelines.<sup>2,3,41</sup> Appropriate post-discharge support and/or contact is often identified as a gap in services, by both patients and carers<sup>8</sup> and hospitals which provide stroke care,<sup>42</sup> and it would be of interest.

Given the lack of effect on most of the outcome measures used in this study, it needs to be considered whether the improvement that was found in some outcomes is sufficient to justify the implementation of the intervention. Whether a stroke support service should continue to be funded if it does not address psychosocial outcomes has been raised in a previous study of stroke family officers support officers.<sup>43</sup> While the resources required to provide this intervention are less intensive than many of the other stroke patient and carer education and support interventions that have been trialled, a cost effectiveness evaluation of this intervention, following refinement of some of its features, is required.

#### Areas for future research

A qualitative component of this study may have enhanced interpretation of the quantitative results and provided further insights into participants' perspectives about components of the intervention. Outcome measures relating to self-efficacy, satisfaction and ratings of the importance of information and feeling informed were developed for this study due to a lack of existing measures and exploration of their psychometric properties, sensitivity to change, and their suitability for people with aphasia would be valuable.

Enhancement of the intervention may be needed to influence psychosocial outcomes. This enhancement may come from combining its provision with other active informational interventions. For example, hands-on practical training for carers has been demonstrated to reduce in patient anxiety and depression and carer anxiety, depression and burden.<sup>44</sup> A recent systematic review of educational needs of patients with stroke and their carers calls for



improvements in stroke education.<sup>4</sup> Enhancement and provision of this tailored stroke education and support package may be one way of addressing this need.

**Conclusion**

The provision of a tailored education and support package resulted in significantly higher self-efficacy in accessing stroke information, feelings of being informed, and satisfaction with information received of stroke patients and their carers. Refinement and enhancement of the package and subsequent evaluation of its effect is required before widespread implementation can be recommended.

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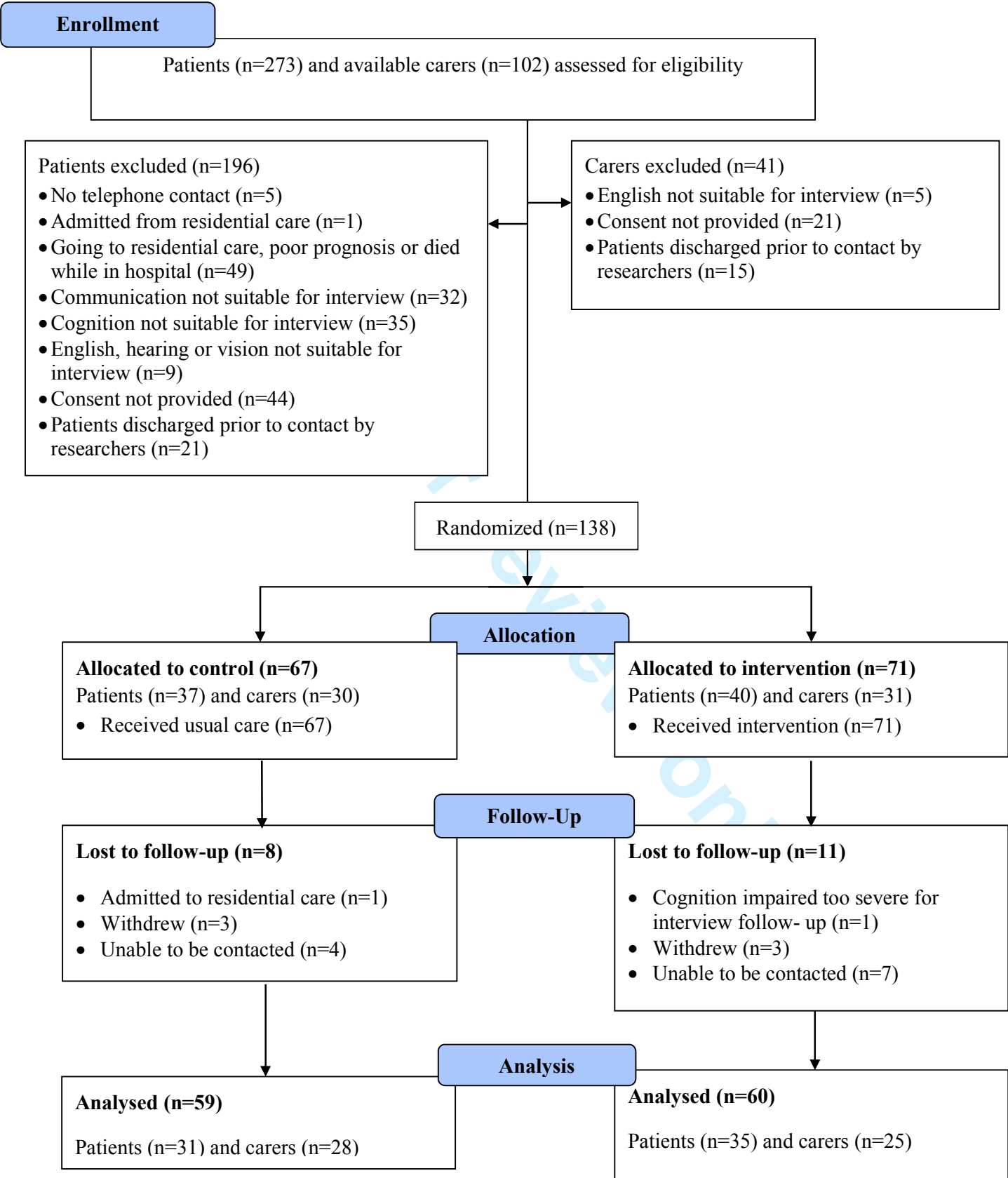
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Figure 1: Flow of participants



**Table 1:** Demographic and clinical characteristics at baseline. Values are numbers (percentages) unless otherwise stated

Variable	Control (n=67)	Intervention (n=71)
Mean age in years (SD; range)	61.4 (12.7; 24-86)	55.2 (16.7; 27-97)
Female gender	36 (53.7)	39 (54.9)
Living with:		
Alone	10 (14.9)	13 (18.3)
Partner / family	57 (85.1)	58 (81.7)
Relationship to patient <sup>a</sup>	(n=30)	(n=31)
Partner	21 (70.0)	20 (64.5)
Child	7 (23.3)	9 (29.0)
Sibling/other	2 (6.7)	2 (6.5)
Mean years of schooling (SD; range)	11.8 (3.6; 2-21)	12.1 (3.3; 6-20)
REALM grade equivalent: <sup>b</sup>	(n=62)	(n=67)
≤ 3rd	0	1 (1.5%)
4 <sup>th</sup> -6 <sup>th</sup>	3 (4.8)	3 (4.5)
7 <sup>th</sup> -8 <sup>th</sup>	19 (30.6)	19 (28.4)
≥9 <sup>th</sup>	40 (64.5)	44 (65.7)



**Table 1 continued:** Demographic and clinical characteristics at baseline

Patient stroke type: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Ischaemic	31 (86.1)	29 (72.5)
Haemorrhagic	5 (13.9)	10 (25)
TIA	0	1 (2.5)
Patient side of stroke: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Left	12 (33.3)	15 (37.5)
Right	21 (58.3)	24 (60.0)
Bilateral	3 (8.3)	1 (2.5)
First-time stroke <sup>c</sup>	(n=37)	(n=40)
	31 (83.8)	27 (67.5)

<sup>a</sup> Carer participants only

<sup>b</sup> Eight patients and one carer were unable to complete the REALM due to poor vision

<sup>c</sup> Patient participants only

<sup>d</sup> One patient’s stroke type and side was missing

**Table 2:** Baseline and 3 month follow-up outcome measures scores

Outcome (score range)	Mean (SD) baseline scores		Mean (SD) follow-up scores		ANCOVA results	
	Control group (n=59)	Intervention group (n=60)	Control group (n=59)	Intervention group (n=60)	Between group difference adjusted mean (95% CI)	p-value
Stroke knowledge (0-25)	17.2 (3.9)	17.5 (3.1)	18.7 (3.5)	19.8 (3.0)	0.9 (-0.4 to 2.2)	0.176
Self-efficacy (1-10)						
Cope with stroke	6.8 (2.6)	7.1 (2.3)	7.7 (1.9)	8.1 (1.8)	0.2 (-0.5 to 0.8)	0.600
Access practical help	7.8 (2.3)	8.2 (2.0)	8.3 (1.9)	8.5 (1.5)	0.2 (-0.4 to 0.9)	0.483
Access emotional help	7.8 (2.4)	8.0 (2.1)	8.1 (2.0)	8.0 (2.1)	0.0 (-0.7 to 0.9)	0.909
Manage stress	7.2 (2.3)	7.5 (2.2)	7.3 (2.1)	7.6 (1.7)	0.2 (-0.5 to 0.9)	0.584

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

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Self-efficacy (1-10) continued						
Access stroke information	7.6 (2.5)	7.8 (2.4)	7.8 (2.2)	8.8 (1.4)	1.0 (0.3 to 1.7)	0.004*
Understand stroke information	7.9 (1.9)	7.9 (2.1)	7.9 (1.9)	8.5 (1.4)	0.6 (-0.1 to 1.2)	0.077
Talk with doctor	8.6 (2.0)	8.9 (1.4)	8.7 (1.5)	8.9 (1.7)	0.1 (-0.5 to 0.8)	0.651
Talk with health professionals	8.5 (1.8)	8.7 (1.8)	8.6 (1.6)	8.7 (1.6)	0.2 (-0.4 to 0.8)	0.567
Prevent (another) stroke	7.0 (2.4)	6.9 (2.7)	6.8 (2.2)	7.3 (2.7)	0.2 (-0.7 to 1.2)	0.608
Anxiety (0-21)	7.5 (4.2)	8.7 (4.5)	6.6 (4.3)	7.3 (4.3)	0.5 ( -1.1 to 2.1)	0.559
Depression (0-21)	5.0 (3.4)	5.4 (3.8)	4.3 (3.5)	4.9 (3.6)	0.6 (-0.7 to 2.0)	0.377
Feeling informed (1-10)	6.1 (2.6)	6.0 (2.3)	7.3 (1.9)	8.2 (1.7)	0.9 (0.2 to 1.6)	0.008*
Importance of information (1-10)	9.9 (0.4)	9.6 (1.2)	9.4 (1.4)	9.5 (1.1)	0.1 (-0.4 to 0.6)	0.615

Table 2 continued: Baseline and 3 month follow-up outcome measures scores

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**Satisfaction with information received (1-10)**

Medical information	6.3 (2.5)	6.5 (2.3)	6.8 (2.6)	8.8 (1.8)	2.0 (1.1 to 2.8)	<0.001*
Practical information	5.9 (2.7)	6.2 (2.7)	7.4 (2.5)	8.5 (1.9)	1.1 (0.3 to 1.9)	0.008*
Service and benefits	5.3 (3.0)	5.8 (2.8)	7.1 (2.7)	7.9 (1.8)	0.9 (0.1 to 1.8)	0.036*
Prevention information	5.8 (2.7)	6.2 (2.7)	6.9 (2.6)	8.6 (1.7)	1.7 (0.9 to 2.5)	<0.001*

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<b>Quality of life (patients) (1-5)</b>	(n=31)	(n=35)	(n=31)	(n=35)	0.1 (-0.2 to 0.4)	0.496
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	3.5 (0.8)	3.6 (0.8)	4.1 (0.7)	4.0 (0.7)		
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<b>Caregiver burden (carers) (0-13)</b>	(n=28)	(n=25)	(n=28)	(n=25)	0.1 (-2.0 to 2.1)	0.932
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	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)		
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\* significant difference between groups

^ f-value indicated underpowering likely

**Table 3:** Satisfaction with intervention components

Intervention component	Participant reported component as useful n (%) (n=60 )	Mean (SD) usefulness rating (1-10)
Written component	53 (88.3)	9.1 (1.4)
Talking to someone face-to-face (in hospital)	58 (96.7)	8.9 (1.6)
Talking to someone over the telephone (following discharge)	45 (75.0)	7.9 (2.3)
Having a telephone support person available if needed	51 (85.0)	8.2 (2.4)

### Authors' contribution

Dr Eames was partially responsible for concept design, and primarily responsible for review of the literature, participant recruitment, data collection, data analysis and interpretation and manuscript preparation. A/Prof. Hoffmann and Prof. Worrall were partially responsible for concept design and also provided peer-review of data analysis and interpretation and manuscript preparation. Dr Read and Dr Wong provided peer-review of data interpretation and manuscript preparation.

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### Data sharing statement

The dataset is available at Dryad repository (provisional doi:10.5061/dryad.hs03q), who will provide a permanent, citable and open access home for the dataset.

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**Randomised controlled trial of an education and support package for stroke patients and their carers**

**Abstract**

**Objective:**

Tailoring stroke information and providing reinforcement opportunities are two strategies proposed to enhance the effectiveness of education. This study aimed to evaluate the effects of an education package which utilised both strategies on the knowledge, health and psychosocial outcomes of stroke patients and carers.

**Design:**

Multi-site, randomised trial comparing usual care with an education and support package

**Setting:**

Two acute stroke units.

**Participants:**

Patients and their carers (N=138) were randomised (control n=67, intervention n=71) of which data for 119 participants (control n=59, intervention n=60) were analysed.

**Intervention:**

The package consisted of a computer-generated, tailored written information booklet and verbal reinforcement provided prior to, and for three months following, discharge.

**Outcome measures:**

Outcome measures were administered prior to hospital discharge and at three month follow-up by blinded assessors. The primary outcome was stroke knowledge (score range: 0-25).

Secondary outcomes were: self-efficacy (1-10), anxiety and depression (0-21), ratings of importance of information (1-10), feelings of being informed (score range: 1-10), satisfaction with information (1-10), caregiver burden (carers) (0-13) and quality of life (patients) (1-5).

### Results:

Intervention group participants reported better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention information (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ). There was no significant effect on other outcomes.

### Conclusions:

Intervention group participants had improved self efficacy for accessing stroke information and satisfaction with information, but other outcomes were not significantly affected.

Evaluation of a more intensive intervention in a trial with a larger sample size is required to establish the value of an educational intervention that uses tailoring and reinforcement strategies.

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Article summary

Article focus:

- Patient and carer education is a crucial component of post-stroke care but little is known about the most effective way of providing it.
- Tailoring stroke information and providing opportunities for reinforcement have been suggested as useful strategies ~~are recommended~~.
- This study aimed to evaluate the effects of an education package which used both of these strategies on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers.

Key messages

- The education and support package included a computer-generated, tailored written information booklet and verbal reinforcement and commenced ~~, provided~~ in hospital and continued during the three months following discharge ~~, after stroke~~.
- The package improved stroke self-efficacy for accessing stroke information and satisfaction with information received.
- The effects of tailored messages and verbal reinforcement on other outcomes, such as knowledge, mood, quality of life/caregiver burden, remains unknown ~~is not known~~.

Strengths and limitations of this study

- This intervention evaluated in this study was theoretically informed, developed with patient and carer input, and expanded ~~built~~ on a previous trial ~~T results. Additionally,~~ the inclusion of both patients and carers enhances the applicability to clinicians ~~health~~.

~~professionals~~ working in this ~~clinical~~ area as ~~(where~~ patients are often seen with their carers or a family member).

- Results may not be generalisable to all patients with stroke. The sample size was small and the study likely to be underpowered. Some of the ~~There was also underpowering of some outcome measures and several~~ s outcome measures lack formal evaluation ~~available~~ formal evaluation of psychometric properties ~~data~~.

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**Introduction**

Stroke information provision is a crucial component of care for patients and carers<sup>1-3</sup>, however their information needs are often poorly met.<sup>4-8</sup> Information needs vary between individuals<sup>9</sup> and tailoring of information to individual patient and/or carer needs is required.<sup>10-13</sup>

Three tailored written information interventions for patients with stroke have been evaluated in randomised trials.<sup>14-16</sup> In an evaluation of booklets that contained information previously presented verbally there were no significant differences in physical or social functioning between groups.<sup>14</sup> Evaluation of individualised information booklets that were verbally reinforced in one session found significantly better stroke knowledge for intervention group patients, but no other between-group differences.<sup>15</sup> In a trial which compared a computer-generated tailored written information booklet ('What you need to know about stroke') with generic non-tailored stroke information, intervention group patients had significantly better satisfaction with information received and their information needs were better met, but no other significant improvements compared to the control group.<sup>16</sup> These studies suggest that while there may be some benefits associated with tailored written information, refinement of tailored stroke educational interventions and further research is required.

A possible mechanism for enhancing the effectiveness of stroke information interventions is suggested in a Cochrane review, in which 'active' interventions (which actively included patients and carers and provided the opportunity to clarify and reinforce information) were found to be more effective at improving patient anxiety and depression than passive ones.<sup>17</sup> Furthermore, because patients and carers continue to have information needs after leaving hospital,<sup>4, 8, 18</sup> continued access to information after discharge is recommended.<sup>1</sup>

In the current study, an education and support package for patients and carers that expanded upon the previously evaluated 'What you need to know about stroke' tailored booklet and provided opportunities for clarification and reinforcement of information both prior to, and following, discharge, was developed. Research into patients' and carer's information needs and format preferences<sup>19</sup> was also used to inform the intervention design, as was the Health Belief Model<sup>20</sup> and adult learning principles. The Health Belief Model has previously been used in the area of stroke as a basis to explore patient beliefs regarding risk-related behaviour change.<sup>21</sup> The model assumes that in order for behaviour change to occur, a person must believe: that they are at risk of a particular illness (perceived susceptibility); that the consequence of that illness is serious (perceived severity); that making the behaviour change can produce a positive outcome (perceived benefit); and that the perceived benefit of behaviour change outweighs any perceived barriers to behaviour change.<sup>20</sup> Another component of the model is the person's self-efficacy (confidence in their ability) to perform a behaviour.<sup>20</sup> As the intervention was targeted at adults, the principles of adult learning were also incorporated in the education package.<sup>22</sup> These principles include consideration of a person's: need to know, self concept, prior experiences, readiness to learn, orientation to learning, and motivation to learn.<sup>22</sup>

The research question addressed by this study was "What are the effects of an education and support package on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers?" The primary aim of this study was to evaluate the effect of this education package on the knowledge of stroke patients and carers; with a secondary aim of evaluating its effect on participants' self-efficacy, mood, feelings of being informed and the

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~~importance of information, satisfaction, and patient quality of life / carer burden-health and psychosocial outcomes of stroke patients and carers.~~

**Methods**

Participants and study design

Eligible patients ~~and carers~~ consecutively identified as nearing discharge from the acute stroke unit of two public, tertiary hospitals in Brisbane, Australia and their carers were invited to participate in this randomised trial. Eligibility criteria included: (1) having, or being a carer for someone with, a current diagnosis of stroke (first or subsequent) or transient ischaemic attack (TIA); (2) not living in residential care prior to admission to hospital, or having residential care as planned discharge destination; (3) contactable by telephone; and (4) adequate English, cognition and communication, vision and hearing to participate in an interview and complete the questionnaire. Members of the treating interdisciplinary team assisted in identifying eligible patients, and available and eligible carers. For example, the treating speech pathologist advised on patients' communication ability, and the treating doctor or occupational therapist advised on patients' cognitive ability. If the patient was ineligible, available carers were still approached.

Procedure

~~Members of the treating intermultidisciplinary team assisted in identifying eligible participants.~~ The lead author obtained informed, written consent and completed the initial interviews. Concealed, random allocation was achieved via sequentially numbered envelopes containing computer-generated random numbers prepared by a person not involved in the study. Paired patient and carer dyads were allocated to the same group. Participants then

received standard care (control group) or standard care and the intervention (intervention group) until three months following discharge.

Outcome measures were administered face-to-face prior to acute stroke unit discharge (mean 12.8, SD 9.3 days since stroke). They were re-administered via telephone three months after discharge (mean 112.1, SD 14.1 days since stroke) by a different researcher who was blind to group allocation. Once completed, this assessor opened a sealed section of the form to determine group allocation and asked intervention group participants additional questions regarding the intervention. A comparison of telephone and face-to-face administration of these measures found no significant differences between the two methods.<sup>23</sup>

Demographic and clinical characteristics were collected at baseline from participant interview and from patients' medical chart. The Rapid Estimate of Adult Literacy in Medicine (REALM)<sup>24</sup> was also administered at baseline as an estimate of participants' reading ability. The REALM is a reading recognition test with good test-re-test reliability and concurrent validity with standardised reading tests.<sup>24</sup> Ethical clearance was obtained from relevant hospital and university ethics committees and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTR Number: ACTRN12608000469314).

#### Intervention

Control group participants received standard stroke unit care (~~which included~~ medical, nursing and allied health assessment and treatment, which included ~~ing the provision of~~ unstructured informal verbal education and advice from various members of the treating team). ~~provided throughout the discharge process. Formal educational opportunities were~~

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~~minimal with~~ No structured stroke education or support groups were offered at either site ~~at~~during ~~the time of recruitment~~this study nor were written materials routinely provided. ~~to~~

Participants in the intervention group received the education and support package in addition to standard care.

The design of the education and support package was informed by recommendations from the literature,<sup>25</sup> and previous research by the author team which explored current practice gaps,<sup>25</sup> patient and carer preferences for receiving information<sup>19</sup> and potential barriers to information provision.<sup>26</sup> The health professional providing the package was the lead author, who is an occupational therapist with clinical experience in stroke rehabilitation, however the intervention was designed so that it could be provided by any health professional who has knowledge and experience in stroke management.

The package consisted of: a previously evaluated and described computer-generated, tailored written information booklet ([www.uq.edu.au/tru/strokebook](http://www.uq.edu.au/tru/strokebook));<sup>16, 27</sup> verbal reinforcement of information up to three times pre-discharge; telephone contact up to three times post-discharge; and a telephone number that participants could call with questions. Participants could tailor the written information by choosing topics from a list of 34 topics and the level of information detail (detailed or brief)<sup>27</sup> (please see online supplementary materials) and the verbal sessions by nominating the topics for discussion. Intervention group participants received the written information and face-to-face sessions prior to discharge interview (please see online supplementary materials). Following discharge, telephone contact to participants was provided by three health ~~professional~~-initiated telephone calls at intervals of approximately one month ~~by~~, over a three month period (please see inline supplementary materials). ~~As~~ The Health Belief Model<sup>20</sup> and adult learning principles<sup>22</sup> ~~were~~ was used to

inform the development of the intervention. ~~As a result,~~ the health professional providing the intervention incorporated the following strategies where possible: assessing knowledge, exploring barriers and ways to overcome them; correcting misinformation; providing specific and personalised information about the risks and seriousness of unhealthy behaviour, and specific details of the benefits of healthy behaviour; providing reassurance and encouraging the use of support networks; using persuasion and training in breaking tasks into smaller steps; and encouraging the use of stress management strategies.

The health professional providing the intervention was not a member of the interdisciplinary team at either stroke unit and approached participants independent of the standard treating team. Face-to-face sessions were conducted at the patients' bedside or in a nearby quiet interview room. In the case of participating dyads (both patient and their carer allocated to the intervention group), participants were offered the choice of combined or separate education sessions. The information needs checklist, intervention protocol and the intervention tracking template are provided as online supplementary materials. Further details of the intervention are available from the author on request.

~~As the intervention also contained information related to secondary stroke prevention and subsequent risk related behaviour change, development of the intervention according to a validated health behaviour change model was required~~

#### Outcome measures

The primary outcome was stroke knowledge and assessed using the 25-item Knowledge of Stroke Questionnaire<sup>16</sup> which has a true/false/don't know response format and has good test-retest reliability.<sup>28</sup> with higher scores indicating better stroke knowledge. Secondary



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outcomes were self-efficacy, anxiety and depression, quality of life (patients) and caregiver burden (carers) and ratings of: being informed; importance of information; and satisfaction with information received. Due to a lack of a suitable existing measure, ~~a new~~<sup>the</sup> tool for assessing self-efficacy in accessing and using stroke information ~~was that was~~ developed for this study, drawing on Lorig and colleagues' Self-efficacy to Perform Self-Management Behaviour measures for chronic disease.<sup>29</sup> It consists of nine items (see Table 2), each scoring self-efficacy on a 1-10 Likert scale, and using a stem statement of "At the moment, how confident are you that you...?"

Anxiety and depression was assessed using the 14-item Hospital Anxiety and Depression Scale (HADS)<sup>30</sup> (scores range from 0-21 for each anxiety and depression subscale), with higher scores indicating higher levels of anxiety or depression. The internal consistency, as indicated by Spearman's correlation, of the HAD's anxiety subscale items has been reported as ranging from +0.76 to +0.41 (p< 0.01 for all items) and for the depression subscale, +0.60 to + 0.30 (all lower than p< 0.02).<sup>30</sup> Self-reported ratings of being informed, the importance of information and satisfaction with information received were assessed using 10-point Likert scales, where 1 = "not at all..." and 10 = "extremely..."

Finally, pPatient-specific quality of life was assessed using the Stroke and Aphasia Quality of Life Scale-39 Generic (SAQOL-39g) which has been validated on patients with and without aphasia.<sup>31</sup> The 39 items, each scored on a Likert scale of 1-5, are organised into three categories: physical, psychosocial and communication. Higher category and total means indicate better quality of life. The SAQOL-39 has acceptable test-retest reliability (intraclass correlation coefficient = 0.89 to 0.98), internal consistency (Cronbach's  $\alpha$  = 0.74 to 0.94), and construct validity (corrected domain-total correlations,  $r$ =0.38 to 0.58; convergent,  $r$ =0.55 to

0.67; discriminant,  $r = 0.02$  to  $0.27$  validity)".<sup>32</sup> ~~The~~ carer-specific measure of burden was assessed using the Caregiver Strain Index (CSI), for which scores range from 0-13 with higher total scores indicating higher burden.<sup>33</sup> It has strong internal consistency (Cronbach's  $\alpha = 0.86$ ), clinical validity and significant correlation with other caregiver burden scales.

~~<sup>34</sup>Self-reported ratings of being informed, the importance of information and satisfaction with information received were assessed using 10-point Likert scales, where 1 = "not at all..." and 10 = "extremely..."~~

Finally, questions were asked of the intervention group participants to obtain feedback on the intervention. These included asking if they had read the booklet, and the usefulness of each of the four components of the intervention on a 1-10 Likert scale, where 1="not at all useful" and 10="extremely useful".

### Sample size and statistical analysis

A sample size calculation was conducted for the primary outcome of stroke knowledge based on data from previous research<sup>16</sup> and on the expectation that a between-group difference of a mean score of 2 would be clinically significant. Assuming equality of groups pre-intervention, using a standard deviation of 3.6, power of 0.8 and a significance level of 0.05 (two-sided), a required sample size of 102 (51 in each group) was predicted. To allow for a possible attrition rate of 25%, a target of 136 participants was set. ~~To identify potential~~

~~underpowering, post-hoc power calculations were conducted for each outcome measure.~~

Statistical analysis was conducted using STATA (version 10) and on an intention-to-treat basis. Because of baseline differences in age between the groups, ANCOVAs were completed

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on follow-up scores for all outcomes. Participants included both patients and carers, with data analysed together.

**Results**

The flow of participants through the trial is presented in Figure 1. Recruitment occurred over a thirteen month period between 2008 and 2009, during which time 273 patients and 102 available carers were assessed for eligibility. Of the 138 participants randomised, 8 control group participants and 11 intervention group participants were lost to follow-up, resulting in an overall follow-up rate of 86%. Demographic and clinical characteristics of participants are presented in Table 1. Just over half of the participants (55.5%) had their paired patient or carer also participating in the study. Baseline and follow-up outcome measure scores are presented in Table 2. Participant mean age at baseline was significantly different between the control and intervention groups (61.8 vs. 55.1years).

At the three month follow-up, there were no significant between-group differences for stroke knowledge. Participants in the intervention group did however, have significantly better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7, p=0.004); feeling informed (MD 0.9, 95% CI 0.2 to 1.6, p=0.008); and satisfaction with information received relating to medical (MD 2.0, 95% CI 1.1 to 2.8, p<0.001); practical (MD 1.1, 95% CI 0.3 to 1.9, p=0.008), services and benefits (MD 0.9, 95% CI 0.1 to 1.8, p=0.036); and secondary prevention (MD 1.7, 95% CI 0.9 to 2.5, p<0.001) (see Table 2). There were no significant between-group differences for the other outcomes.

### Intervention provision and feedback

The mean number of contacts prior to discharge was 1.3 (SD 0.6, range 1-3) and 2.5 (SD 0.9 range 0-3) following discharge. The mean total minutes of contact prior to discharge was 25.5 (SD 14.9, range 2-60) and following discharge was 8.6 (SD 8.3, range 1-43). The mean length of total contact time (face-to-face and telephone) was 59.1 minutes (SD 40.0, range 9-196). Only one participant (a patient) made use of the telephone support number to contact the health professional with a question. Please see Table 3 which presents the proportion of participants who reported each component of the intervention as useful and the mean usefulness rating. Fifty-five (91.7%) of participants in the intervention group stated that they had read the written booklet.

### **Discussion**

The provision of a tailored education and support package to stroke patients and carers resulted in participants reporting significantly higher self-efficacy for accessing stroke information, feelings of being informed, and satisfaction with information received. SA strengths of this study include: its randomised controlled design; an intervention whose design was informed by a series of previous studies with the intended population; and Additionally, the inclusion of both patients and carers which enhances the applicability to health professionals working in this clinical area. It is noted that this combined analysis does not allow separation of patient and carer outcomes, which may be of interest to clinicians and researchers. Both patients and carers were recruited as participants for this study as the intervention was designed to meet the needs of both patients and carers and this also allowed maximization of the power of the study.

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~~A One~~ limitation of this study is that these results may not be generalisable to patients with more severe cognitive impairment or aphasia or to patients who require high-level residential care and their carers. These populations are commonly excluded from studies of educational interventions and identifying effective educational resources, as well as methods by which to conduct this research are current research gaps. Under powering and Post hoc power analysis indicated that the primary and several of the secondary outcome measures used in this trial were underpowered and the possibility of a Type II error should also be considered. Finally, a three month follow-up period may also not have been sufficient to see the full influence of the intervention.

Our study used a 25-item stroke knowledge test, which allowed comparison with the previous RCT of the tailored written booklet used as part of the current study's intervention.<sup>16</sup> Hoffmann and colleagues found a non-significant between-group difference of 0.1,<sup>16</sup> while for this study it was 0.9, yet also non-significant. A more sensitive outcome measure or variations to the intervention (such as greater intensity) may be required to observe a significant between group difference in stroke knowledge. A significant improvement in knowledge in the intervention group had been found by Lowe et al.<sup>15</sup> The content of Lowe's booklets contained both general and patient-specific stroke information, while the content of our booklets was entirely tailored by the participants' choice of content and level of information. This more complete tailoring may make it difficult to accurately assess the knowledge of all participants using a uniform measure as not all participants will have been exposed to the same content. Use of a knowledge outcome measure that is more sensitive to

differing content exposure or variations to the intervention (such as greater intensity) may be required to detect differences achieved from a tailored intervention.

Insufficient intensity of the intervention may have also contributed to the lack of significant differences between the groups for the other outcomes, along with underpowering of the study. Although a total of up to six contacts with the health professional providing the intervention were offered, some participants declined some of these. This may have diluted the effect of the intervention. Possible explanations for the amount of post-discharge contact being considerably less than the amount of pre-discharge contact include: reduced tolerance for long telephone conversations due to stroke-or carer-related fatigue; difficulty engaging some participants in discussion over the telephone; or needs other than information taking a higher priority once a patient has left the acute ward. Additionally, although care was taken to ensure the telephone contacts occurred at times suitable to the participant, participants may have felt that they did not have 'time to talk' or were not as prepared for the discussion as they could have been. This emphasises the need to complete a regular, formal review of information needs.<sup>18, 35</sup> Formalising the information provision by scheduling an outpatient appointment may overcome some barriers of telephone communication, but may create other difficulties for patients and carers such as community mobility. The use of alternative communications such as computer-based Skype or video-conferencing may be more resource- and time-efficient, and more convenient for patients and/or carers who experience difficulties with community mobility and transport post-stroke. Alternative solutions should be explored, depending on the resources and infrastructure available to stroke patients, their carers, and the health facility in which the health professionals work. Information needs persist and change beyond hospital discharge<sup>4, 36</sup> and health professionals need to find ways to continually meet these changing needs.

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In the current study participants in the intervention group had significantly better self-efficacy for accessing stroke information. Several components of the intervention may have directly contributed to this, including: the written information booklet contained a detailed ‘Where to get help’ section, and the health professional providing the intervention modelled strategies which encouraged the use of support networks and explored barriers to accessing them and ways overcome these. Several health education theories describe self-efficacy as an important precursor to performance of a task.<sup>20</sup> This has important implications for the abilities of patients with stroke and their carers to meet ongoing information needs, as it suggests that the intervention may empower them to independently access stroke information even after the intervention period ceased. Facilitating self-efficacy has been found to improve longer-term health outcomes in patients with chronic health conditions.<sup>37</sup>

In the current study participants in the intervention group also demonstrated better satisfaction than control group participants. Higher satisfaction was also found by Hoffmann et al.<sup>16</sup> ~~However the current study did not find a significant improvement in knowledge in the intervention group which had been found by Lowe et al (Lowe, 2007 #97). The content of Lowe’s booklets contained both general and patient specific stroke information, while the content of our booklets was entirely tailored by the participants’ choice of content and level of information. This more complete tailoring may make it difficult to accurately assess the knowledge of all participants using a uniform measure as not all participants will have been exposed to the same content. Perhaps a knowledge outcome measure that is more sensitive to differing content exposure is required to detect differences achieved from a tailored intervention.~~

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The intervention group participants rated all four intervention components highly, including the post-discharge options of talking to someone over the telephone and having a telephone support person available if needed. A Cochrane review of health professional-initiated telephone contact with patients following hospital discharge concluded that the effect of this medium on patient outcomes is currently inconclusive.<sup>38</sup> While this review included studies which involved patients from various diagnostic groups, it did not include any studies specifically with stroke patients. The needs of stroke patients and their carers post-discharge ~~can~~ differ quite substantially to those of other patient groups and stroke-specific studies evaluating this are needed. Stroke patients and carers have reported satisfaction with receiving telephone support when provided in combination with face-to-face provision<sup>39</sup> and a desire to receive telephone support as a follow-up to face-to-face provision.<sup>40</sup>

The high ranking of the usefulness of having someone to call with questions was surprising given that this option was utilised by only one participant. It may be that participants did not use this option because the health professional who provided the intervention appropriately elicited and addressed information needs during the health professional-initiated contacts, or that intervention group participants accessed other sources of information to ask additional questions. Nevertheless, it appears that participants in this study were satisfied to know that there was someone to call, even if they did not utilise the service. Whether this 'call in' component of the intervention would have been better utilised had the follow-up period been longer is also unknown. The need to provide contact details for any questions that may arise following discharge is acknowledged in national and international stroke care guidelines.<sup>2,3,</sup>

<sup>41</sup>Appropriate post-discharge support and/or contact is often identified as a gap in services, by both patients and carers<sup>8</sup> and hospitals which provide stroke care.<sup>42</sup> and it would be of interest.



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Given the lack of effect on most of the outcome measures used in this study, it needs to be considered whether the improvement that was found in some outcomes is sufficient to justify the implementation of the intervention. Whether a stroke support service should continue to be funded if it does not address psychosocial outcomes has been raised in a previous study of stroke family officers support officers.<sup>43</sup> While the resources required to provide this intervention are less intensive than many of the other stroke patient and carer education and support interventions that have been trialled, a cost effectiveness evaluation of this intervention, following refinement of some of its features, is required.

Areas for future research

A qualitative component of this study may have enhanced interpretation of the quantitative results and provided further insights into participants’ perspectives about components of the intervention. Outcome measures relating to self-efficacy, satisfaction and ratings of the importance of information and feeling informed were developed for this study due to a lack of existing measures and exploration of their psychometric properties, sensitivity to change, and their suitability for people with aphasia would be valuable.

Enhancement of the intervention may be needed to influence psychosocial outcomes. This enhancement may come from combining its provision with other active informational interventions. For example, hands-on practical training for carers has been demonstrated to reduce in patient anxiety and depression and carer anxiety, depression and burden.<sup>44</sup> A recent systematic review of educational needs of patients with stroke and their carers calls for

improvements in stroke education.<sup>4</sup> Enhancement and provision of this tailored stroke ~~education and support information~~ package may be one way of addressing this need.

## Conclusion

The provision of a tailored education and support package resulted in significantly ~~higher~~<sup>better</sup> self-efficacy in accessing stroke information, feelings of being informed, and satisfaction with information received ~~of stroke patients and their carers~~. ~~Refinement and~~<sup>Further</sup> enhancement of the package and ~~subsequent~~ evaluation of its effect ~~on other health outcomes~~ is required ~~before widespread implementation can be recommended~~. ~~Tailored stroke information should be an essential component of post-stroke care~~.

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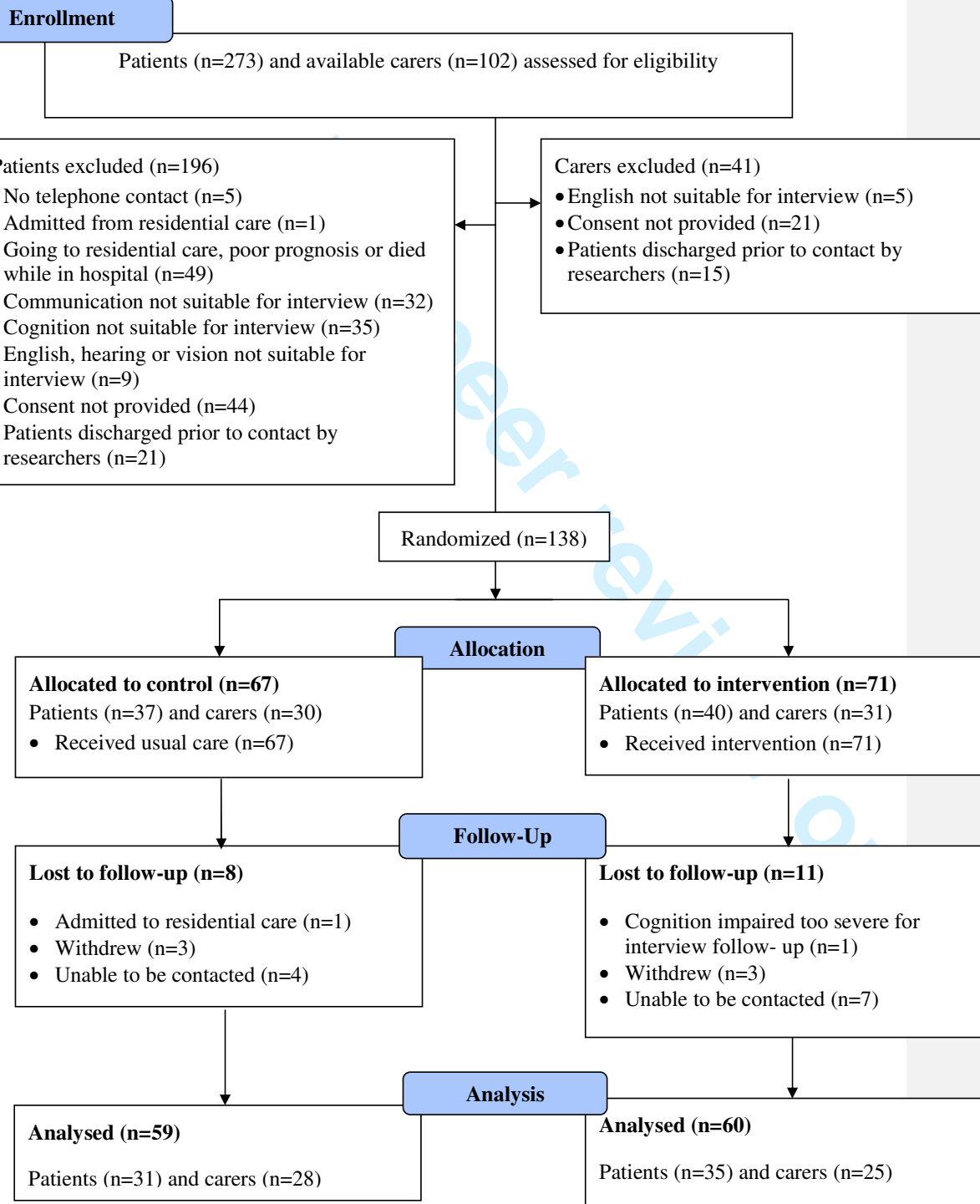
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**Figure 1:** Flow of participants



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**Table 1:** Demographic and clinical characteristics at baseline. Values are numbers (percentages) unless otherwise stated

Variable	Control (n=67)	Intervention (n=71)
Mean age in years (SD; range)	61.4 (12.7; 24-86)	55.2 (16.7; 27-97)
Female gender	36 (53.7)	39 (54.9)
Living with:		
Alone	10 (14.9 )	13 (18.3)
Partner / family	57 (85.1)	58 (81.7)
Relationship to patient <sup>a</sup>	(n=30)	(n=31)
Partner	21 (70.0)	20 (64.5)
Child	7 (23.3)	9 (29.0)
Sibling/other	2 (6.7)	2 (6.5)
Mean years of schooling (SD; range)	11.8 (3.6; 2-21)	12.1 (3.3; 6-20)
REALM grade equivalent: <sup>b</sup>	(n=62)	(n=67)
≤ 3rd	0	1 (1.5%)
4 <sup>th</sup> -6 <sup>th</sup>	3 (4.8)	3 (4.5)
7 <sup>th</sup> -8 <sup>th</sup>	19 (30.6)	19 (28.4)
≥9 <sup>th</sup>	40 (64.5)	44 (65.7)

**Table 1 continued:** Demographic and clinical characteristics at baseline

Patient stroke type: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Ischaemic	31 (86.1)	29 (72.5)
Haemorrhagic	5 (13.9)	10 (25)
TIA	0	1 (2.5)
Patient side of stroke: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Left	12 (33.3)	15 (37.5)
Right	21 (58.3)	24 (60.0)
Bilateral	3 (8.3)	1 (2.5)
First-time stroke <sup>c</sup>	(n=37)	(n=40)
	31 (83.8)	27 (67.5)

<sup>a</sup> Carer participants only

<sup>b</sup> Eight patients and one carer were unable to complete the REALM due to poor vision

<sup>c</sup> Patient participants only

<sup>d</sup> One patient's stroke type and side was missing

**Table 2:** Baseline and 3 month follow-up outcome measures scores

Outcome (score range)	Mean (SD) baseline scores		Mean (SD) follow-up scores		ANCOVA results	
	Control group (n=59)	Intervention group (n=60)	Control group (n=59)	Intervention group (n=60)	Between group difference adjusted mean (95% CI)	p-value
Stroke knowledge (0-25)	17.2 (3.9)	17.5 (3.1)	18.7 (3.5)	19.8 (3.0)	0.9 (-0.4 to 2.2)	0.176
Self-efficacy (1-10)						
Cope with stroke	6.8 (2.6)	7.1 (2.3)	7.7 (1.9)	8.1 (1.8)	0.2 (-0.5 to 0.8)	0.600
Access practical help	7.8 (2.3)	8.2 (2.0)	8.3 (1.9)	8.5 (1.5)	0.2 (-0.4 to 0.9)	0.483
Access emotional help	7.8 (2.4)	8.0 (2.1)	8.1 (2.0)	8.0 (2.1)	0.0 (-0.7 to 0.9)	0.909
Manage stress	7.2 (2.3)	7.5 (2.2)	7.3 (2.1)	7.6 (1.7)	0.2 (-0.5 to 0.9)	0.584

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

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**Self-efficacy (1-10) continued**

Access stroke information	7.6 (2.5)	7.8 (2.4)	7.8 (2.2)	8.8 (1.4)	1.0 (0.3 to 1.7)	0.004*
Understand stroke information	7.9 (1.9)	7.9 (2.1)	7.9 (1.9)	8.5 (1.4)	0.6 (-0.1 to 1.2)	0.077
Talk with doctor	8.6 (2.0)	8.9 (1.4)	8.7 (1.5)	8.9 (1.7)	0.1 (-0.5 to 0.8)	0.651
Talk with health professionals	8.5 (1.8)	8.7 (1.8)	8.6 (1.6)	8.7 (1.6)	0.2 (-0.4 to 0.8)	0.567
Prevent (another) stroke	7.0 (2.4)	6.9 (2.7)	6.8 (2.2)	7.3 (2.7)	0.2 (-0.7 to 1.2)	0.608
<b>Anxiety (0-21)</b>	7.5 (4.2)	8.7 (4.5)	6.6 (4.3)	7.3 (4.3)	0.5 (-1.1 to 2.1)	0.559
<b>Depression (0-21)</b>	5.0 (3.4)	5.4 (3.8)	4.3 (3.5)	4.9 (3.6)	0.6 (-0.7 to 2.0)	0.377
<b>Feeling informed (1-10)</b>	6.1 (2.6)	6.0 (2.3)	7.3 (1.9)	8.2 (1.7)	0.9 (0.2 to 1.6)	0.008*
<b>Importance of information (1-10)</b>	9.9 (0.4)	9.6 (1.2)	9.4 (1.4)	9.5 (1.1)	0.1 (-0.4 to 0.6)	0.615

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

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Satisfaction with information received (1-10)						
Medical information	6.3 (2.5)	6.5 (2.3)	6.8 (2.6)	8.8 (1.8)	2.0 (1.1 to 2.8)	<0.001*
Practical information	5.9 (2.7)	6.2 (2.7)	7.4 (2.5)	8.5 (1.9)	1.1 (0.3 to 1.9)	0.008*
Service and benefits	5.3 (3.0)	5.8 (2.8)	7.1 (2.7)	7.9 (1.8)	0.9 (0.1 to 1.8)	0.036*
Prevention information	5.8 (2.7)	6.2 (2.7)	6.9 (2.6)	8.6 (1.7)	1.7 (0.9 to 2.5)	<0.001*
Quality of life (patients) (1-5)						
	(n=31)	(n=35)	(n=31)	(n=35)	0.1 (-0.2 to 0.4)	0.496
	3.5 (0.8)	3.6 (0.8)	4.1 (0.7)	4.0 (0.7)		
Caregiver burden (carers) (0-13)						
	(n=28)	(n=25)	(n=28)	(n=25)	0.1 (-2.0 to 2.1)	0.932
	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)		

\* significant difference between groups      ^ f-value indicated underpowering likely

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**Table 3:** Satisfaction with intervention components

Intervention component	Participant reported component as useful n (%) (n=60 )	Mean (SD) usefulness rating (1-10)
Written component	53 (88.3)	9.1 (1.4)
Talking to someone face-to-face (in hospital)	58 (96.7)	8.9 (1.6)
Talking to someone over the telephone (following discharge)	45 (75.0)	7.9 (2.3)
Having a telephone support person available if needed	51 (85.0)	8.2 (2.4)

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**Authors' contribution**

Dr Eames was partially responsible for concept design, and primarily responsible for review of the literature, participant recruitment, data collection, data analysis and interpretation and manuscript preparation. A/Prof. Hoffmann and Prof. Worrall were partially responsible for concept design and also provided peer-review of data analysis and interpretation and manuscript preparation. Dr Read and Dr Wong provided peer-review of data interpretation and manuscript preparation.

**Funding statement**

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**Data sharing statement**

The dataset is available at Dryad repository (provisional doi:10.5061/dryad.hs03q), who will provide a permanent, citable and open access home for the dataset.



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6-7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6-7,
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7



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3		11b	If relevant, description of the similarity of interventions	7
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
6				
7	<b>Results</b>			
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
9	diagram is strongly		were analysed for the primary outcome	
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	11 & 21
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
12		14b	Why the trial ended or was stopped	N/A
13				
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	21-22
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	21
16			by original assigned groups	
17				
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	24-26
19	estimation		precision (such as 95% confidence interval)	
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	N/A
22			pre-specified from exploratory	
23				
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
25				
26	<b>Discussion</b>			
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-16
30				
31	<b>Other information</b>			
32	Registration	23	Registration number and name of trial registry	2 & 7
33	Protocol	24	Where the full trial protocol can be accessed, if available	N/A
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	28
35				

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37 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

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### Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of the study as randomized	1
Authors *	Contact details for the corresponding author	Separate attachment
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	1
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	1
Interventions	Interventions intended for each group	1
Objective	Specific objective or hypothesis	1
Outcome	Clearly defined primary outcome for this report	1-2
Randomization	How participants were allocated to interventions	1
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	1
Results		
Numbers randomized	Number of participants randomized to each group	1
Recruitment	Trial status	1
Numbers analysed	Number of participants analysed in each group	1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	2
Harms	Important adverse events or side effects	N/A
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	2
Funding	Source of funding	End of article

*\*this item is specific to conference abstracts*

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-Please complete option 1 or 2 as appropriate and sign below. If you answered "yes" to any of the 5 questions relating to financial competing interests (or you wish to disclose a non-financial competing interest), you should write a statement below.

Sally Eames    ☐ None declared    Please insert the following statement under competing interests

Tammy Hoffmann    ☐ None declared    Please insert the following statement under competing interests

TH receives income from subscription fees to the tailored stroke education package which enable technical maintenance of the website and database.

Linda Worrall    ☐ None declared    Please insert the following statement under competing interests

Stephen Read    ☐ None declared    Please insert the following statement under competing interests

Andrew Wong    ☐ None declared    Please insert the following statement under competing interests

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Title of paper: Randomised controlled trial of an education and support package for stroke patients and their carers

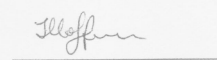
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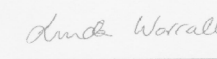
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Sally Eames



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Linda Worrall

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Title of paper: Randomised controlled trial of an education and support package for stroke patients and their carers

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Signature (all authors to sign):

*(Print name)*

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Signature (all authors to sign):

*(Print name)*

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**Randomised controlled trial of an education and support package for stroke patients and their carers**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002538.R2
Article Type:	Research
Date Submitted by the Author:	16-Mar-2013
Complete List of Authors:	Eames, Sally; Brighton Health Campus & Services, Hoffmann, Tammy Worrall, Linda Read, Stephen Wong, Andrew
<b>Primary Subject Heading</b>:	Neurology
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Stroke < NEUROLOGY, EDUCATION & TRAINING (see Medical Education & Training), REHABILITATION MEDICINE

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Manuscripts

**Randomised controlled trial of an education and support package for stroke patients and their carers**

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**Keywords:** Stroke < NEUROLOGY, EDUCATION & TRAINING (see Medical Education & Training),  
REHABILITATION MEDICINE

**Word count:** 3924

**Abstract**

**Objective:**

Tailoring stroke information and providing reinforcement opportunities are two strategies proposed to enhance the effectiveness of education. This study aimed to evaluate the effects of an education package which utilised both strategies on the knowledge, health and psychosocial outcomes of stroke patients and carers.



**Design:**

Multi-site, randomised trial comparing usual care with an education and support package

**Setting:**

Two acute stroke units.

**Participants:**

Patients and their carers (N=138) were randomised (control n=67, intervention n=71) of which data for 119 participants (control n=59, intervention n=60) were analysed.

**Intervention:**

The package consisted of a computer-generated, tailored written information booklet and verbal reinforcement provided prior to, and for three months following, discharge.

**Outcome measures:**

Outcome measures were administered prior to hospital discharge and at three month follow-up by blinded assessors. The primary outcome was stroke knowledge (score range: 0-25). Secondary outcomes were: self-efficacy (1-10), anxiety and depression (0-21), ratings of importance of information (1-10), feelings of being informed (score range: 1-10), satisfaction with information (1-10), caregiver burden (carers) (0-13) and quality of life (patients) (1-5).

**Results:**

Intervention group participants reported better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7, p=0.004); feeling informed (MD 0.9, 95% CI 0.2 to 1.6, p=0.008); and satisfaction with medical (MD 2.0, 95% CI 1.1 to 2.8, p<0.001); practical (MD 1.1, 95% CI 0.3 to 1.9, p=0.008), services

and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention information (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ). There was no significant effect on other outcomes.

**Conclusions:**

Intervention group participants had improved self efficacy for accessing stroke information and satisfaction with information, but other outcomes were not significantly affected. Evaluation of a more intensive intervention in a trial with a larger sample size is required to establish the value of an educational intervention that uses tailoring and reinforcement strategies.

ACTRN12608000469314

## Article summary

### Article focus:

- Patient and carer education is a crucial component of post-stroke care but little is known about the most effective way of providing it.
- Tailoring stroke information and providing opportunities for reinforcement have been suggested as useful strategies.
- This study aimed to evaluate the effects of an education package which used both of these strategies on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers.

### Key messages

- The education and support package included a computer-generated, tailored written information booklet and verbal reinforcement and commenced in hospital and continued during the three months following discharge.
- The package improved stroke self-efficacy for accessing stroke information and satisfaction with information received.
- The effects of tailored messages and verbal reinforcement on other outcomes, such as knowledge, mood, quality of life/caregiver burden, remains unknown.

### Strengths and limitations of this study

- This intervention evaluated in this study was theoretically informed, developed with patient and carer input, and expanded on a previous trial. The inclusion of both patients and carers enhances the applicability to clinicians working in this area as patients are often seen with their carers or a family member.

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- Results may not be generalisable to all patients with stroke. The sample size was small and the study likely to be underpowered. Some of the outcome measures lack formal evaluation of psychometric properties.

For peer review only

## Introduction

Stroke information provision is a crucial component of care for patients and carers<sup>1-3</sup>, however their information needs are often poorly met.<sup>4-8</sup> Information needs vary between individuals<sup>9</sup> and tailoring of information to individual patient and/or carer needs is required.<sup>10-13</sup>

Three tailored written information interventions for patients with stroke have been evaluated in randomised trials.<sup>14-16</sup> In an evaluation of booklets that contained information previously presented verbally there were no significant differences in physical or social functioning between groups.<sup>14</sup> Evaluation of individualised information booklets that were verbally reinforced in one session found significantly better stroke knowledge for intervention group patients, but no other between-group differences.<sup>15</sup> In a trial which compared a computer-generated tailored written information booklet ('What you need to know about stroke') with generic non-tailored stroke information, intervention group patients had significantly better satisfaction with information received and their information needs were better met, but no other significant improvements compared to the control group.<sup>16</sup> These studies suggest that while there may be some benefits associated with tailored written information, refinement of tailored stroke educational interventions and further research is required.

A possible mechanism for enhancing the effectiveness of stroke information interventions is suggested in a Cochrane review, in which 'active' interventions (which actively included patients and carers and provided the opportunity to clarify and reinforce information) were found to be more effective at improving patient anxiety and depression than passive ones.<sup>17</sup> Furthermore, because patients and carers continue to have information needs after leaving hospital,<sup>4, 8, 18</sup> continued access to information after discharge is recommended.<sup>1</sup>

In the current study, an education and support package for patients and carers that expanded upon the previously evaluated ‘What you need to know about stroke’ tailored booklet and provided opportunities for clarification and reinforcement of information both prior to, and following, discharge, was developed. Research into patients’ and carer’s information needs and format preferences<sup>19</sup> was also used to inform the intervention design, as was the Health Belief Model<sup>20</sup> and adult learning principles. The Health Belief Model has previously been used in the area of stroke as a basis to explore patient beliefs regarding risk-related behaviour change.<sup>21</sup> The model assumes that in order for behaviour change to occur, a person must believe: that they are at risk of a particular illness (perceived susceptibility); that the consequence of that illness is serious (perceived severity); that making the behaviour change can produce a positive outcome (perceived benefit); and that the perceived benefit of behaviour change outweighs any perceived barriers to behaviour change.<sup>20</sup> Another component of the model is the person’s self-efficacy (confidence in their ability) to perform a behaviour.<sup>20</sup> As the intervention was targeted at adults, the principles of adult learning were also incorporated in the education package.<sup>22</sup> These principles include consideration of a person’s: need to know, self concept, prior experiences, readiness to learn, orientation to learning, and motivation to learn.<sup>22</sup>

The research question addressed by this study was “What are the effects of an education and support package on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers?” The primary aim of this study was to evaluate the effect of this education package on the knowledge of stroke patients and carers; with a secondary aim of evaluating its effect on participants’ self-efficacy, mood, feelings of being informed and the importance of information, satisfaction, and patient quality of life / carer burden.

## Methods

### Participants and study design

Eligible patients consecutively identified as nearing discharge from the acute stroke unit of two public, tertiary hospitals in Brisbane, Australia and their carers were invited to participate in this randomised trial. Eligibility criteria included: (1) having, or being a carer for someone with, a current diagnosis of stroke (first or subsequent) or transient ischaemic attack (TIA); (2) not living in residential care prior to admission to hospital, or having residential care as planned discharge destination; (3) contactable by telephone; and (4) adequate English, cognition and communication, vision and hearing to participate in an interview and complete the questionnaire. Members of the treating interdisciplinary team assisted in identifying eligible patients, and available and eligible carers. For example, the treating speech pathologist advised on patients' communication ability, and the treating doctor or occupational therapist advised on patients' cognitive ability. If the patient was ineligible, available carers were still approached.

### Procedure

The lead author obtained informed, written consent and completed the initial interviews. Concealed, random allocation was achieved via sequentially numbered envelopes containing computer-generated random numbers prepared by a person not involved in the study. Paired patient and carer dyads were allocated to the same group. Participants then received standard care (control group) or standard care and the intervention (intervention group) until three months following discharge.

Outcome measures were administered face-to-face prior to acute stroke unit discharge (mean 12.8, SD 9.3 days since stroke). They were re-administered via telephone three months after discharge (mean 112.1, SD 14.1 days since stroke) by a different researcher who was blind to group allocation. Once completed, this assessor opened a sealed section of the form to determine group allocation and asked intervention group participants additional questions regarding the intervention. A comparison of telephone and face-to-face administration of these measures found no significant differences between the two methods.<sup>23</sup>

Demographic and clinical characteristics were collected at baseline from participant interview and from patients' medical chart. The Rapid Estimate of Adult Literacy in Medicine (REALM)<sup>24</sup> was also administered at baseline as an estimate of participants' reading ability. The REALM is a reading recognition test with good test-re-test reliability and concurrent validity with standardised reading tests.<sup>24</sup> Ethical clearance was obtained from relevant hospital and university ethics committees and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTR Number: ACTRN12608000469314).

Intervention

Control group participants received standard stroke unit care (medical, nursing and allied health assessment and treatment, which included the provision of unstructured informal verbal education and advice from various members of the treating team). Structured stroke education or support groups were not offered at either site during the time of this study nor were written materials routinely provided. Participants in the intervention group received the education and support package in addition to standard care.



The design of the education and support package was informed by recommendations from the literature,<sup>25</sup> and previous research by the author team which explored current practice gaps,<sup>25</sup> patient and carer preferences for receiving information<sup>19</sup> and potential barriers to information provision.<sup>26</sup> The health professional providing the package was the lead author, who is an occupational therapist with clinical experience in stroke rehabilitation however the intervention was designed so that it could be provided by any health professional who has knowledge and experience in stroke management.

The package consisted of: a previously evaluated and described computer-generated, tailored written information booklet ([www.uq.edu.au/tru/strokebook](http://www.uq.edu.au/tru/strokebook));<sup>16, 27</sup> verbal reinforcement of information up to three times pre-discharge; telephone contact up to three times post-discharge; and a telephone number that participants could call with questions. Participants could tailor the written information by choosing topics from a list of 34 topics and the level of information detail (detailed or brief)<sup>27</sup> (please see online Appendix A for this checklist) and the verbal sessions by nominating the topics for discussion. Intervention group participants received the written information and face-to-face sessions prior to discharge interview (please see online Appendix B and C for the Intervention Protocol and Intervention Template). Following discharge, telephone contact to participants was provided by three health professional-initiated telephone calls at intervals of approximately one month, over a three month period (please see online Appendix B and C). As the Health Belief Model<sup>20</sup> and adult learning principles<sup>22</sup> was used to inform the development of the intervention, the health professional providing the intervention incorporated the following strategies where possible: assessing knowledge, exploring barriers and ways to overcome them; correcting misinformation; providing specific and personalised information about the risks and seriousness of unhealthy behaviour, and specific details of the benefits of healthy behaviour;

providing reassurance and encouraging the use of support networks; using persuasion and training in breaking tasks into smaller steps; and encouraging the use of stress management strategies.

The health professional providing the intervention was not a member of the interdisciplinary team at either stroke unit and approached participants independent of the standard treating team. Face-to-face sessions were conducted at the patients' bedside or in a nearby quiet interview room. In the case of participating dyads (both patient and their carer allocated to the intervention group), participants were offered the choice of combined or separate education sessions. The information needs checklist, intervention protocol and the intervention tracking template are provided as online supplementary materials. Further details of the intervention are available from the author on request.

Outcome measures

The primary outcome was stroke knowledge and assessed using the 25-item Knowledge of Stroke Questionnaire <sup>16</sup> which has a true/false/don't know response format and has good test-retest reliability, <sup>28</sup> with higher scores indicating better stroke knowledge. Secondary outcomes were self-efficacy, anxiety and depression, quality of life (patients) and caregiver burden (carers) and ratings of: being informed; importance of information; and satisfaction with information received. Due to a lack of a suitable existing measure, the tool for assessing self-efficacy in accessing and using stroke information that was developed for this study, drawing on Lorig and colleagues' Self-efficacy to Perform Self-Management Behaviour measures for chronic disease. <sup>29</sup> It consists of nine items (see Table 2), each scoring self-

efficacy on a 1-10 Likert scale, and using a stem statement of “At the moment, how confident are you that you...?”

Anxiety and depression was assessed using the 14-item Hospital Anxiety and Depression Scale (HADS)<sup>30</sup> (scores range from 0-21 for each anxiety and depression subscale), with higher scores indicating higher levels of anxiety or depression. The internal consistency, as indicated by Spearman’s correlation, of the HAD’s anxiety subscale items has been reported as ranging from +0.76 to +0.41 ( $p < 0.01$  for all items) and for the depression subscale, +0.60 to +0.30 (all lower than  $p < 0.02$ ).<sup>30</sup> Self-reported ratings of being informed, the importance of information and satisfaction with information received were assessed using 10-point Likert scales, where 1 = “not at all...” and 10 = “extremely...”

Finally, patient-specific quality of life was assessed using the Stroke and Aphasia Quality of Life Scale-39 Generic (SAQOL-39g) which has been validated on patients with and without aphasia.<sup>31</sup> The 39 items, each scored on a Likert scale of 1-5, are organised into three categories: physical, psychosocial and communication. Higher category and total means indicate better quality of life. The SAQOL-39 has acceptable test-retest reliability (intraclass correlation coefficient = 0.89 to 0.98), internal consistency (Cronbach’s  $\alpha = 0.74$  to 0.94), and construct validity (corrected domain-total correlations,  $r = 0.38$  to 0.58; convergent,  $r = 0.55$  to 0.67; discriminant,  $r = 0.02$  to 0.27 validity).<sup>32</sup> A carer-specific measure of burden was assessed using the Caregiver Strain Index (CSI), for which scores range from 0-13 with higher total scores indicating higher burden.<sup>33</sup> It has strong internal consistency (Cronbach’s  $\alpha = 0.86$ ),<sup>33</sup> clinical validity and significant correlation with other caregiver burden scales.<sup>34</sup>

Finally, questions were asked of the intervention group participants to obtain feedback on the intervention. These included asking if they had read the booklet, and the usefulness of each of the four components of the intervention on a 1-10 Likert scale, where 1=“not at all useful” and 10=“extremely useful”.

Sample size and statistical analysis

A sample size calculation was conducted for the primary outcome of stroke knowledge based on data from previous research<sup>16</sup> and on the expectation that a between-group difference of a mean score of 2 would be clinically significant. Assuming equality of groups pre-intervention, using a standard deviation of 3.6, power of 0.8 and a significance level of 0.05 (two-sided), a required sample size of 102 (51 in each group) was predicted. To allow for a possible attrition rate of 25%, a target of 136 participants was set. Statistical analysis was conducted using STATA (version 10) and on an intention-to-treat basis. Because of baseline differences in age between the groups, ANCOVAs were completed on follow-up scores for all outcomes. Participants included both patients and carers, with data analysed together.

**Results**

The flow of participants through the trial is presented in Figure 1. Recruitment occurred over a thirteen month period between 2008 and 2009, during which time 273 patients and 102 available carers were assessed for eligibility. Of the 138 participants randomised, 8 control group participants and 11 intervention group participants were lost to follow-up, resulting in an overall follow-up rate of 86%. Demographic and clinical characteristics of participants are presented in Table 1. Just over half of the participants (55.5%) had their paired patient or

carer also participating in the study. Baseline and follow-up outcome measure scores are presented in Table 2. Participant mean age at baseline was significantly different between the control and intervention groups (61.8 vs. 55.1 years).

At the three month follow-up, there were no significant between-group differences for stroke knowledge. Participants in the intervention group did however, have significantly better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with information received relating to medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ) (see Table 2). There were no significant between-group differences for the other outcomes.

#### Intervention provision and feedback

The mean number of contacts prior to discharge was 1.3 (SD 0.6, range 1-3) and 2.5 (SD 0.9 range 0-3) following discharge. The mean total minutes of contact prior to discharge was 25.5 (SD 14.9, range 2-60) and following discharge was 8.6 (SD 8.3, range 1-43). The mean length of total contact time (face-to-face and telephone) was 59.1 minutes (SD 40.0, range 9-196). Only one participant (a patient) made use of the telephone support number to contact the health professional with a question. Please see Table 3 which presents the proportion of participants who reported each component of the intervention as useful and the mean usefulness rating. Fifty-five (91.7%) of participants in the intervention group stated that they

had read the written booklet. There were no differences between patients and carers in the use and satisfaction with the intervention (data not shown).

**Discussion**

The provision of a tailored education and support package to stroke patients and carers resulted in participants reporting significantly higher self-efficacy for accessing stroke information, feelings of being informed, and satisfaction with information received. Strengths of this study include: it’s randomised controlled design; an intervention whose design was informed by a series of previous studies with the intended population; and the inclusion of both patients and carers which enhances the applicability to health professionals working in this clinical area. It is noted that this combined analysis does not allow separation of patient and carer outcomes, which may be of interest to clinicians and researchers (please see online Appendix D which details separate patient and carers scores at baseline and follow-up). Both patients and carers were recruited as participants for this study as the intervention was designed to meet the needs of both patients and carers and this also allowed maximization of the power of the study.

A limitation of this study is that these results may not be generalisable to patients with more severe cognitive impairment or aphasia or to patients who require high-level residential care and their carers. These populations are commonly excluded from studies of educational interventions and identifying effective educational resources, as well as methods by which to conduct this research are current research gaps. Under powering and the possibility of a Type

II error should also be considered. Finally, a three month follow-up period may also not have been sufficient to see the full influence of the intervention.

Our study used a 25-item stroke knowledge test, which allowed comparison with the previous RCT of the tailored written booklet used as part of the current study's intervention.<sup>16</sup>

Hoffmann and colleagues found a non-significant between-group difference of 0.1,<sup>16</sup> while for this study it was 0.9, yet also non-significant.. A significant improvement in knowledge in the intervention group had been found by Lowe et al.<sup>15</sup> The content of Lowe's booklets contained both general and patient-specific stroke information, while the content of our booklets was entirely tailored by the participants' choice of content and level of information. This more complete tailoring may make it difficult to accurately assess the knowledge of all participants using a uniform measure as not all participants will have been exposed to the same content. Use of a knowledge outcome measure that is more sensitive to differing content exposure or variations to the intervention (such as greater intensity) may be required to detect differences achieved from a tailored intervention.

Insufficient intensity of the intervention may have also contributed to the lack of significant differences between the groups for the other outcomes, along with underpowering of the study. Although a total of up to six contacts with the health professional providing the intervention were offered, some participants declined some of these. This may have diluted the effect of the intervention. Possible explanations for the amount of post-discharge contact being considerably less than the amount of pre-discharge contact include: reduced tolerance for long telephone conversations due to stroke-or carer-related fatigue; difficulty engaging some participants in discussion over the telephone; or needs other than information taking a

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3 higher priority once a patient has left the acute ward. Additionally, although care was taken to  
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5 ensure the telephone contacts occurred at times suitable to the participant, participants may  
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7 have felt that they did not have ‘time to talk’ or were not as prepared for the discussion as  
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9 they could have been. This emphasises the need to complete a regular, formal review of  
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11 information needs.<sup>18, 35</sup> Formalising the information provision by scheduling an outpatient  
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13 appointment may overcome some barriers of telephone communication, but may create other  
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15 difficulties for patients and carers such as community mobility. The use of alternative  
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17 communications such as computer-based video-conferencing may be more resource- and  
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19 time-efficient, and more convenient for patients and/or carers who experience difficulties  
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21 with community mobility and transport post-stroke. Alternative solutions should be  
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23 explored, depending on the resources and infrastructure available to stroke patients, their  
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25 carers, and the health facility in which the health professionals work. Information needs  
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27 persist and change beyond hospital discharge<sup>4, 36</sup> and health professionals need to find ways  
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29 to continually meet these changing needs.  
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36 In the current study participants in the intervention group had significantly better self-efficacy  
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38 for accessing stroke information. Several components of the intervention may have directly  
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40 contributed to this, including: the written information booklet contained a detailed ‘Where to  
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42 get help’ section, and the health professional providing the intervention modelled strategies  
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44 which encouraged the use of support networks and explored barriers to accessing them and  
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46 ways overcome these. Several health education theories describe self-efficacy as an important  
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48 precursor to performance of a task.<sup>20</sup> This has important implications for the abilities of  
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50 patients with stroke and their carers to meet ongoing information needs, as it suggests that the  
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52 intervention may empower them to independently access stroke information even after the  
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3 intervention period ceased. Facilitating self-efficacy has been found to improve longer-term  
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5 health outcomes in patients with chronic health conditions.<sup>37</sup>  
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10 In the current study participants in the intervention group also demonstrated better  
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12 satisfaction than control group participants. Higher satisfaction was also found by Hoffmann  
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14 et al.<sup>16</sup> The intervention group participants rated all four intervention components highly,  
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16 including the post-discharge options of talking to someone over the telephone and having a  
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18 telephone support person available if needed. A Cochrane review of health professional-  
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20 initiated telephone contact with patients following hospital discharge concluded that the  
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22 effect of this medium on patient outcomes is currently inconclusive.<sup>38</sup> While this review  
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24 included studies which involved patients from various diagnostic groups, it did not include  
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26 any studies specifically with stroke patients. The needs of stroke patients and their carers  
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28 post-discharge differ quite substantially to those of other patient groups and stroke-specific  
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30 studies evaluating this are needed. Stroke patients and carers have reported satisfaction with  
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32 receiving telephone support when provided in combination with face-to-face provision<sup>39</sup> and  
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34 a desire to receive telephone support as a follow-up to face-to-face provision.<sup>40</sup>  
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41 The high ranking of the usefulness of having someone to call with questions was surprising  
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43 given that this option was utilised by only one participant. It may be that participants did not  
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45 use this option because the health professional who provided the intervention appropriately  
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47 elicited and addressed information needs during the health professional-initiated contacts, or  
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49 that intervention group participants accessed other sources of information to ask additional  
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51 questions. Nevertheless, it appears that participants in this study were satisfied to know that  
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53 there was someone to call, even if they did not utilise the service. Whether this 'call in'  
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55 component of the intervention would have been better utilised had the follow-up period been  
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longer is also unknown. The need to provide contact details for any questions that may arise following discharge is acknowledged in national and international stroke care guidelines.<sup>2,3,</sup>  
<sup>41</sup>Appropriate post-discharge support and/or contact is often identified as a gap in services, by both patients and carers<sup>8</sup> and hospitals which provide stroke care,<sup>42</sup> and it would be of interest.

Given the lack of effect on most of the outcome measures used in this study, it needs to be considered whether the improvement that was found in some outcomes is sufficient to justify the implementation of the intervention. Whether a stroke support service should continue to be funded if it does not address psychosocial outcomes has been raised in a previous study of stroke family officers support officers.<sup>43</sup> While the resources required to provide this intervention are less intensive than many of the other stroke patient and carer education and support interventions that have been trialled, a cost effectiveness evaluation of this intervention, following refinement of some of its features, is required.

Areas for future research

A qualitative component of this study may have enhanced interpretation of the quantitative results and provided further insights into participants’ perspectives about components of the intervention. Outcome measures relating to self-efficacy, satisfaction and ratings of the importance of information and feeling informed were developed for this study due to a lack of existing measures and exploration of their psychometric properties, sensitivity to change, and their suitability for people with aphasia would be valuable.

Enhancement of the intervention may be needed to influence psychosocial outcomes. This enhancement may come from combining its provision with other active informational interventions. For example, hands-on practical training for carers has been demonstrated to reduce in patient anxiety and depression and carer anxiety, depression and burden.<sup>44</sup> A recent systematic review of educational needs of patients with stroke and their carers calls for improvements in stroke education.<sup>4</sup> Enhancement and provision of this tailored stroke education and support package may be one way of addressing this need.

## Conclusion

The provision of a tailored education and support package resulted in significantly higher self-efficacy in accessing stroke information, feelings of being informed, and satisfaction with information received of stroke patients and their carers. Refinement and enhancement of the package and subsequent evaluation of its effect is required before widespread implementation can be recommended.

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## Figure legends

**Figure 1:** Flow of participants

For peer review only

**Table 1:** Demographic and clinical characteristics at baseline. Values are numbers (percentages) unless otherwise stated

Variable	Control (n=67)	Intervention (n=71)
Mean age in years (SD; range)	61.4 (12.7; 24-86)	55.2 (16.7; 27-97)
Female gender	36 (53.7)	39 (54.9)
Living with:		
Alone	10 (14.9 )	13 (18.3)
Partner / family	57 (85.1)	58 (81.7)
Relationship to patient <sup>a</sup>	(n=30)	(n=31)
Partner	21 (70.0)	20 (64.5)
Child	7 (23.3)	9 (29.0)
Sibling/other	2 (6.7)	2 (6.5)
Mean years of schooling (SD; range)	11.8 (3.6; 2-21)	12.1 (3.3; 6-20)
REALM grade equivalent: <sup>b</sup>	(n=62)	(n=67)
≤ 3rd	0	1 (1.5%)
4 <sup>th</sup> -6 <sup>th</sup>	3 (4.8)	3 (4.5)
7 <sup>th</sup> -8 <sup>th</sup>	19 (30.6)	19 (28.4)
≥9 <sup>th</sup>	40 (64.5)	44 (65.7)

**Table 1 continued:** Demographic and clinical characteristics at baseline

Patient stroke type: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Ischaemic	31 (86.1)	29 (72.5)
Haemorrhagic	5 (13.9)	10 (25)
TIA	0	1 (2.5)
Patient side of stroke: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Left	12 (33.3)	15 (37.5)
Right	21 (58.3)	24 (60.0)
Bilateral	3 (8.3)	1 (2.5)
First-time stroke <sup>c</sup>	(n=37)	(n=40)
	31 (83.8)	27 (67.5)

<sup>a</sup> Carer participants only

<sup>b</sup> Eight patients and one carer were unable to complete the REALM due to poor vision

<sup>c</sup> Patient participants only

<sup>d</sup> One patient's stroke type and side was missing

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**Table 2:** Baseline and 3 month follow-up outcome measures scores

Outcome (score range)	Mean (SD) baseline scores		Mean (SD) follow-up scores		ANCOVA results	
	Control group (n=59)	Intervention group (n=60)	Control group (n=59)	Intervention group (n=60)	Between group difference adjusted mean (95% CI)	p-value
Stroke knowledge (0-25)	17.2 (3.9)	17.5 (3.1)	18.7 (3.5)	19.8 (3.0)	0.9 (-0.4 to 2.2)	0.176
Self-efficacy (1-10)						
Cope with stroke	6.8 (2.6)	7.1 (2.3)	7.7 (1.9)	8.1 (1.8)	0.2 (-0.5 to 0.8)	0.600
Access practical help	7.8 (2.3)	8.2 (2.0)	8.3 (1.9)	8.5 (1.5)	0.2 (-0.4 to 0.9)	0.483
Access emotional help	7.8 (2.4)	8.0 (2.1)	8.1 (2.0)	8.0 (2.1)	0.0 (-0.7 to 0.9)	0.909
Manage stress	7.2 (2.3)	7.5 (2.2)	7.3 (2.1)	7.6 (1.7)	0.2 (-0.5 to 0.9)	0.584

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

**Self-efficacy (1-10) continued**

Access stroke information	7.6 (2.5)	7.8 (2.4)	7.8 (2.2)	8.8 (1.4)	1.0 (0.3 to 1.7)	0.004*
Understand stroke information	7.9 (1.9)	7.9 (2.1)	7.9 (1.9)	8.5 (1.4)	0.6 (-0.1 to 1.2)	0.077
Talk with doctor	8.6 (2.0)	8.9 (1.4)	8.7 (1.5)	8.9 (1.7)	0.1 (-0.5 to 0.8)	0.651
Talk with health professionals	8.5 (1.8)	8.7 (1.8)	8.6 (1.6)	8.7 (1.6)	0.2 (-0.4 to 0.8)	0.567
Prevent (another) stroke	7.0 (2.4)	6.9 (2.7)	6.8 (2.2)	7.3 (2.7)	0.2 (-0.7 to 1.2)	0.608
<b>Anxiety (0-21)</b>	7.5 (4.2)	8.7 (4.5)	6.6 (4.3)	7.3 (4.3)	0.5 (-1.1 to 2.1)	0.559
<b>Depression (0-21)</b>	5.0 (3.4)	5.4 (3.8)	4.3 (3.5)	4.9 (3.6)	0.6 (-0.7 to 2.0)	0.377
<b>Feeling informed (1-10)</b>	6.1 (2.6)	6.0 (2.3)	7.3 (1.9)	8.2 (1.7)	0.9 (0.2 to 1.6)	0.008*
<b>Importance of information (1-10)</b>	9.9 (0.4)	9.6 (1.2)	9.4 (1.4)	9.5 (1.1)	0.1 (-0.4 to 0.6)	0.615

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

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<b>Satisfaction with information received (1-10)</b>						
Medical information	6.3 (2.5)	6.5 (2.3)	6.8 (2.6)	8.8 (1.8)	2.0 (1.1 to 2.8)	<0.001*
Practical information	5.9 (2.7)	6.2 (2.7)	7.4 (2.5)	8.5 (1.9)	1.1 (0.3 to 1.9)	0.008*
Service and benefits	5.3 (3.0)	5.8 (2.8)	7.1 (2.7)	7.9 (1.8)	0.9 (0.1 to 1.8)	0.036*
Prevention information	5.8 (2.7)	6.2 (2.7)	6.9 (2.6)	8.6 (1.7)	1.7 (0.9 to 2.5)	<0.001*
<b>Quality of life (patients) (1-5)</b>	(n=31)	(n=35)	(n=31)	(n=35)	0.1 (-0.2 to 0.4)	0.496
	3.5 (0.8)	3.6 (0.8)	4.1 (0.7)	4.0 (0.7)		
<b>Caregiver burden (carers) (0-13)</b>	(n=28)	(n=25)	(n=28)	(n=25)	0.1 (-2.0 to 2.1)	0.932
	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)		

\* significant difference between groups      ^ f-value indicated underpowering likely

**Table 3:** Satisfaction with intervention components

Intervention component	Participant reported component as useful n (%) (n=60 )	Mean (SD) usefulness rating (1-10)
Written component	53 (88.3)	9.1 (1.4)
Talking to someone face-to-face (in hospital)	58 (96.7)	8.9 (1.6)
Talking to someone over the telephone (following discharge)	45 (75.0)	7.9 (2.3)
Having a telephone support person available if needed	51 (85.0)	8.2 (2.4)

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**Authors’ contribution**

Dr Eames was partially responsible for concept design, and primarily responsible for review of the literature, participant recruitment, data collection, data analysis and interpretation and manuscript preparation. A/Prof. Hoffmann and Prof. Worrall were partially responsible for concept design and also provided peer-review of data analysis and interpretation and manuscript preparation. Dr Read and Dr Wong provided peer-review of data interpretation and manuscript preparation.

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**Data sharing statement**

The dataset is available at Dryad repository (provisional doi:10.5061/dryad.hs03q), who will provide a permanent, citable and open access home for the dataset.



## Appendix

Appendix A “What *you* need to know about stroke” checklist

Appendix B Intervention protocol

Appendix C Intervention template

Appendix D Separate patient and carer scores

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Appendix A “What *you* need to know about stroke” checklist

(Please see attached file.)

For peer review only

Appendix B Intervention protocol

For peer review only

**Intervention Protocol – Stroke information service**

Prior to discharge:

First contact will occur prior to Acute Stroke Unit (ASU) discharge, after the initial interview is completed.

- It will involve an introduction to the tailored written education booklet (participants will be shown an example) and participants’ selection of topics of interest to them.
- One copy will be printed for each client (paired clients and carers will have one between two unless specifically requested – highlighting sections that were ‘client or carer only requested’).

On second contact the booklet will be provided and layout will be briefly explained.

- Content will be discussed, with a particular focus on keys areas (such as risk factors and behaviours to address these) and any questions answered.
- Explanation of the scope and limits of the intervention will be provided.
- Participants will then be offered a third face-to-face session to discuss the information and/or ask questions after they have had time to read the booklet.
- A suitable day/time for the first follow-up telephone call (approximately 3-4 weeks later) will be confirmed, with a prompt to look through the booklet before the telephone call to remind themselves of any questions and to have booklet at hand during the telephone call.
- Participants will be provided with the support service’s contact telephone number if they need to contact the service in the interim, in addition to reinforcement of other suitable contacts (for example, their GP, service providers, treating team).
- If clients are discharged before this visit, the written education booklet will be posted out and a telephone call made to the participant a few days after its arrival.

After ASU discharge:

The first telephone follow-up call will be made to participant approximately 3-4 weeks post ASU discharge

- Verbal reinforcement of the content of booklet will occur (all/some of topics, as per client preference/needs) with a particular focus on risk factors and behaviours to address these.
- Any questions from the book/in general will be answered.
- A suitable time for the second follow-up call (in approximately 1 month) will be made, with a prompt to look through the booklet before the telephone call to remind themselves of any questions and to have booklet at hand during the telephone).
- Confirmation of the support services' contact telephone number if they need to call in the interim and reinforce other suitable contacts (their GP, service providers, treating team).

Second follow-up telephone call:

- ~Verbal reinforcement of content of booklet (all/some of topics - as per client preference/needs) with a particular focus on risk factors and behaviours to address these.
- Any questions from the booklet/in general will be answered.
- Review of information needs. If participants indicate any other topics of interest, these will be posted out to add to booklet.
- Participants will be offered a final call (in approximately 1 month) if desired, and reminded that they can contact the support service for up to three months post ASU discharge.

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Appendix C    Intervention template

For peer review only

Intervention provided		Date	Details								Time taken		
											Direct contact	Indirect contact	
			Didactic	Combo	Ref to written	Q&A	Discussion	Link to services	P/S (modelling)	Role Play	Other		
Checklist of topics (after initial interview and randomisation)													
Booklet printed (and posted)													
<b>1<sup>st</sup> contact face-to-face</b> (after consent and Initial Interview)	Attempts to contact												
	Explanation of lx (what it is and is not)												
	Provision of education booklet with explanation of layout		Booklet posted (____) and lx completed over t/p <input type="checkbox"/>										
	Reinforcement of booklet topics..... AND delivery style used												
<b>2<sup>nd</sup> contact face-to-face</b>	Attempts to contact		Not completed as booklet posted & 1 <sup>st</sup> contact completed over t/p <input type="checkbox"/> OR client d/c prior <input type="checkbox"/>										
	Reinforcement of booklet topics..... AND delivery style used												

	Questions asked and answered...													
Intervention provided		Date	Details										Time taken	
			Didactic	Combo	Ref to written	Q&A	Discussion	Link to services	P/S (modelling)	Role Play	Other	Direct contact	Indirect contact	
3 <sup>rd</sup> contact face-to-face (optional)	Questions asked and answered...													
	Reinforcement of booklet topics..... AND delivery style used													
	Confirm first t/p follow-up contact day/time (~1/12) AND service ph no for Qs													
	Not completed (client/carer declined) <input type="checkbox"/> OR client discharged <input type="checkbox"/>													
4 <sup>th</sup> contact telephone (3-4 weeks post d/c):	Attempts to contact													
	Questions asked and answered...													
	Reinforcement of booklet topics..... AND delivery style used													



	Confirm next t/p next follow-up contact day/time (~1/12) AND service ph no for Qs													
Intervention provided		Date	Details										Time taken	
			Didactic	Combo	Ref to written	Q&A	Discussion	Link to services	P/S (modelling)	Role Play	Other	Direct contact	Indirect contact	
5 <sup>th</sup> contact telephone (~2 month post d/c):	Attempts to contact													
	Questions asked and answered...													
	Reinforcement of booklet topics..... AND delivery style used													
	Offer final t/p follow-up, confirm contact day/time (~1/12) AND service ph no for Qs													
	If decline final f/u call, clarify date of service cessation and remind of f/u interview arrangements Not completed (client/carers declined) <input type="checkbox"/>													
6 <sup>th</sup> contact telephone (~3 months post d/c; at least 1	Questions asked and answered...													
	Reinforcement of booklet													

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week before f/u interview due):	topics.....												
	AND delivery style												
	Clarify date of service end & remind of f/u IV												

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Appendix D Separate patient and carer scores

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Outcome (score range)	Patients				Carers			
	Mean (SD) baseline scores		Mean (SD) follow-up scores		Mean (SD) baseline scores		Mean (SD) follow-up scores	
	Control group (n=31)	Intervention group (n=35)	Control group (n=31)	Intervention group (n=35)	Control group (n=28)	Intervention group (n=25)	Control group (n=28)	Intervention group (n=25)
Stroke knowledge (0-25)	15.6 (3.7)	16.8 (3.0)	17.4 (3.4)	19.3 (2.7)	18.9 (3.4)	18.4 (3.2)	20.2 (3.0)	20.4 (3.3)
Self-efficacy (1-10)								
Cope with stroke	5.9 (3.0)	7.2 (2.5)	7.5 (2.0)	8.1 (1.7)	7.8 (1.6)	7.1 (2.1)	8.0 (1.7)	8.0 (1.9)
Access practical help	7.6 (2.5)	8.5 (1.7)	8.2 (2.0)	8.5 (1.4)	8.0 (2.0)	7.7 (2.4)	8.3 (1.8)	8.5 (1.7)
Access emotional help	7.5 (2.8)	8.0 (2.1)	8.2 (2.1)	8.0 (1.9)	8.2 (1.8)	8.0 (2.1)	8.1 (1.9)	8.0 (2.4)
Manage stress	6.6 (2.8)	7.7 (2.2)	7.1 (2.2)	7.6 (1.8)	7.8 (1.5)	7.3 (2.3)	7.6 (1.9)	7.5 (1.5)

## Appendix D continued

## Self-efficacy (1-10) continued

Access stroke information	7.2 (2.7)	7.6 (2.5)	7.6 (2.3)	8.7 (1.7)	8.1 (2.1)	7.9 (2.2)	7.9 (2.1)	8.9 (1.0)
Understand stroke information	7.5 (2.2)	7.9 (2.3)	7.5(2.0)	8.4 (1.5)	8.3 (1.5)	8.0 (1.7)	8.3 (1.7)	8.5 (1.3)
Talk with doctor	8.4 (2.4)	8.8 (1.4)	8.7 (1.5)	8.9 (1.7)	8.8 (1.6)	9.0 (1.4)	8.8 (1.6)	8.8 (1.8)
Talk with health professionals	8.0 (2.3)	8.5 (1.8)	8.3 (1.9)	8.6 (1.6)	9.1 (1.0)	8.9 (1.8)	9.0 (1.1)	8.8 (1.7)
Prevent (another) stroke	7.6 (2.4)	7.4 (2.4)	6.4 (2.2)	7.5 (2.6)	6.4 (2.3)	6.1 (2.9)	6.8 (2.2)	6.9 (3.0)
Anxiety (0-21)	6.8 (4.1)	7.0 (3.4)	6.4 (4.6)	6.8 (4.0)	8.3 (4.2)	11.0 (4.7)	6.9 (4.1)	8.1 (4.6)
Depression (0-21)	5.2 (3.8)	4.4 (3.0)	5.0 (4.1)	5.2 (3.7)	4.8 (3.1)	6.7 (4.4)	3.5 (2.5)	4.5 (3.8)
Feeling informed (1-10)	5.7 (3.1)	5.9 (2.6)	7.1 (2.3)	8.3 (1.8)	6.5 (1.8)	6.1 (2.1)	7.6 (1.4)	8.2 (1.6)
Importance of information (1-10)	9.8 (0.5)	9.5 (1.3)	9.2 (1.7)	9.3 (1.3)	9.9 (0.3)	9.7 (1.1)	9.6 (0.8)	9.7 (0.9)

Appendix D continued

<b>Satisfaction with information received (1-10)</b>								
Medical information	6.2 (2.9)	6.9 (2.4)	6.6 (2.9)	8.6 (1.9)	6.4 (1.8)	6.0 (2.1)	7.0 (2.2)	9.0 (1.7)
Practical information	6.1 (2.8)	6.7 (2.7)	7.6 (2.2)	8.5 (1.6)	5.6 (2.7)	5.4 (2.6)	7.1 (2.7)	8.4 (2.2)
Service and benefits	5.4 (3.0)	6.6 (2.6)	7.0 (2.8)	7.8 (1.7)	5.2 (3.2)	4.7 (2.8)	7.3 (2.6)	8.1 (1.9)
Prevention information	5.9 (2.7)	6.9 (2.3)	7.2 (2.5)	8.7 (1.6)	5.7 (2.7)	5.2 (3.0)	6.6 (2.7)	8.4 (1.8)
<b>Quality of life</b> (patients) (1-5)	3.5 (0.8)	3.6 (0.9)	4.0 (0.7)	4.0 (0.7)	N/A	N/A	N/A	N/A
<b>Caregiver burden</b> (carers) (0-13)	N/A	N/A	N/A	N/A	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)

# **Randomised controlled trial of an education and support package for stroke patients and their carers**

## **Abstract**

### **Objective:**

Tailoring stroke information and providing reinforcement opportunities are two strategies proposed to enhance the effectiveness of education. This study aimed to evaluate the effects of an education package which utilised both strategies on the knowledge, health and psychosocial outcomes of stroke patients and carers.

### **Design:**

Multi-site, randomised trial comparing usual care with an education and support package

### **Setting:**

Two acute stroke units.

### **Participants:**

Patients and their carers (N=138) were randomised (control n=67, intervention n=71) of which data for 119 participants (control n=59, intervention n=60) were analysed.

### **Intervention:**

The package consisted of a computer-generated, tailored written information booklet and verbal reinforcement provided prior to, and for three months following, discharge.

### **Outcome measures:**

Outcome measures were administered prior to hospital discharge and at three month follow-up by blinded assessors. The primary outcome was stroke knowledge (score range: 0-25). Secondary outcomes were: self-efficacy (1-10), anxiety and depression (0-21), ratings of importance of information (1-10), feelings of being informed (score range: 1-10), satisfaction with information (1-10), caregiver burden (carers) (0-13) and quality of life (patients) (1-5).

**Results:**

Intervention group participants reported better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7, p=0.004); feeling informed (MD 0.9, 95% CI 0.2 to 1.6, p=0.008); and satisfaction with medical (MD 2.0, 95% CI 1.1 to 2.8, p<0.001); practical (MD 1.1, 95% CI 0.3 to 1.9, p=0.008), services and benefits (MD 0.9, 95% CI 0.1 to 1.8, p=0.036); and secondary prevention information (MD 1.7, 95% CI 0.9 to 2.5, p<0.001). There was no significant effect on other outcomes.

**Conclusions:**

Intervention group participants had improved self efficacy for accessing stroke information and satisfaction with information, but other outcomes were not significantly affected. Evaluation of a more intensive intervention in a trial with a larger sample size is required to establish the value of an educational intervention that uses tailoring and reinforcement strategies.

ACTRN12608000469314



## Article summary

### Article focus:

- Patient and carer education is a crucial component of post-stroke care but little is known about the most effective way of providing it.
- Tailoring stroke information and providing opportunities for reinforcement have been suggested as useful strategies.
- This study aimed to evaluate the effects of an education package which used both of these strategies on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers.

### Key messages

- The education and support package included a computer-generated, tailored written information booklet and verbal reinforcement and commenced in hospital and continued during the three months following discharge.
- The package improved stroke self-efficacy for accessing stroke information and satisfaction with information received.
- The effects of tailored messages and verbal reinforcement on other outcomes, such as knowledge, mood, quality of life/caregiver burden, remains unknown.

### Strengths and limitations of this study

- This intervention evaluated in this study was theoretically informed, developed with patient and carer input, and expanded on a previous trial. The inclusion of both patients and carers enhances the applicability to clinicians working in this area as patients are often seen with their carers or a family member.

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- Results may not be generalisable to all patients with stroke. The sample size was small and the study likely to be underpowered. Some of the outcome measures lack formal evaluation of psychometric properties.

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## Introduction

Stroke information provision is a crucial component of care for patients and carers<sup>1-3</sup>, however their information needs are often poorly met.<sup>4-8</sup> Information needs vary between individuals<sup>9</sup> and tailoring of information to individual patient and/or carer needs is required.<sup>10-13</sup>

Three tailored written information interventions for patients with stroke have been evaluated in randomised trials.<sup>14-16</sup> In an evaluation of booklets that contained information previously presented verbally there were no significant differences in physical or social functioning between groups.<sup>14</sup> Evaluation of individualised information booklets that were verbally reinforced in one session found significantly better stroke knowledge for intervention group patients, but no other between-group differences.<sup>15</sup> In a trial which compared a computer-generated tailored written information booklet ('What you need to know about stroke') with generic non-tailored stroke information, intervention group patients had significantly better satisfaction with information received and their information needs were better met, but no other significant improvements compared to the control group.<sup>16</sup> These studies suggest that while there may be some benefits associated with tailored written information, refinement of tailored stroke educational interventions and further research is required.

A possible mechanism for enhancing the effectiveness of stroke information interventions is suggested in a Cochrane review, in which 'active' interventions (which actively included patients and carers and provided the opportunity to clarify and reinforce information) were found to be more effective at improving patient anxiety and depression than passive ones.<sup>17</sup> Furthermore, because patients and carers continue to have information needs after leaving hospital,<sup>4, 8, 18</sup> continued access to information after discharge is recommended.<sup>1</sup>

In the current study, an education and support package for patients and carers that expanded upon the previously evaluated ‘What you need to know about stroke’ tailored booklet and provided opportunities for clarification and reinforcement of information both prior to, and following, discharge, was developed. Research into patients’ and carer’s information needs and format preferences<sup>19</sup> was also used to inform the intervention design, as was the Health Belief Model<sup>20</sup> and adult learning principles. The Health Belief Model has previously been used in the area of stroke as a basis to explore patient beliefs regarding risk-related behaviour change.<sup>21</sup> The model assumes that in order for behaviour change to occur, a person must believe: that they are at risk of a particular illness (perceived susceptibility); that the consequence of that illness is serious (perceived severity); that making the behaviour change can produce a positive outcome (perceived benefit); and that the perceived benefit of behaviour change outweighs any perceived barriers to behaviour change.<sup>20</sup> Another component of the model is the person’s self-efficacy (confidence in their ability) to perform a behaviour.<sup>20</sup> As the intervention was targeted at adults, the principles of adult learning were also incorporated in the education package.<sup>22</sup> These principles include consideration of a person’s: need to know, self concept, prior experiences, readiness to learn, orientation to learning, and motivation to learn.<sup>22</sup>

The research question addressed by this study was “What are the effects of an education and support package on the knowledge, health, psychosocial and satisfaction outcomes of stroke patients and carers?” The primary aim of this study was to evaluate the effect of this education package on the knowledge of stroke patients and carers; with a secondary aim of evaluating its effect on participants’ self-efficacy, mood, feelings of being informed and the importance of information, satisfaction, and patient quality of life / carer burden.

## Methods

### Participants and study design

Eligible patients consecutively identified as nearing discharge from the acute stroke unit of two public, tertiary hospitals in Brisbane, Australia and their carers were invited to participate in this randomised trial. Eligibility criteria included: (1) having, or being a carer for someone with, a current diagnosis of stroke (first or subsequent) or transient ischaemic attack (TIA); (2) not living in residential care prior to admission to hospital, or having residential care as planned discharge destination; (3) contactable by telephone; and (4) adequate English, cognition and communication, vision and hearing to participate in an interview and complete the questionnaire. Members of the treating interdisciplinary team assisted in identifying eligible patients, and available and eligible carers. For example, the treating speech pathologist advised on patients' communication ability, and the treating doctor or occupational therapist advised on patients' cognitive ability. If the patient was ineligible, available carers were still approached.

### Procedure

The lead author obtained informed, written consent and completed the initial interviews. Concealed, random allocation was achieved via sequentially numbered envelopes containing computer-generated random numbers prepared by a person not involved in the study. Paired patient and carer dyads were allocated to the same group. Participants then received standard care (control group) or standard care and the intervention (intervention group) until three months following discharge.

Outcome measures were administered face-to-face prior to acute stroke unit discharge (mean 12.8, SD 9.3 days since stroke). They were re-administered via telephone three months after discharge (mean 112.1, SD 14.1 days since stroke) by a different researcher who was blind to group allocation. Once completed, this assessor opened a sealed section of the form to determine group allocation and asked intervention group participants additional questions regarding the intervention. A comparison of telephone and face-to-face administration of these measures found no significant differences between the two methods.<sup>23</sup>

Demographic and clinical characteristics were collected at baseline from participant interview and from patients' medical chart. The Rapid Estimate of Adult Literacy in Medicine (REALM)<sup>24</sup> was also administered at baseline as an estimate of participants' reading ability. The REALM is a reading recognition test with good test-re-test reliability and concurrent validity with standardised reading tests.<sup>24</sup> Ethical clearance was obtained from relevant hospital and university ethics committees and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTR Number: ACTRN12608000469314).

Intervention

Control group participants received standard stroke unit care (medical, nursing and allied health assessment and treatment, which included the provision of unstructured informal verbal education and advice from various members of the treating team). ~~No~~ structured stroke education or support groups were not offered at either site during the time of this study nor were written materials routinely provided. Participants in the intervention group received the education and support package in addition to standard care.

The design of the education and support package was informed by recommendations from the literature,<sup>25</sup> and previous research by the author team which explored current practice gaps,<sup>25</sup> patient and carer preferences for receiving information<sup>19</sup> and potential barriers to information provision.<sup>26</sup> The health professional providing the package was the lead author, who is an occupational therapist with clinical experience in stroke rehabilitation however the intervention was designed so that it could be provided by any health professional who has knowledge and experience in stroke management.

The package consisted of: a previously evaluated and described computer-generated, tailored written information booklet ([www.uq.edu.au/tru/strokebook](http://www.uq.edu.au/tru/strokebook));<sup>16, 27</sup> verbal reinforcement of information up to three times pre-discharge; telephone contact up to three times post-discharge; and a telephone number that participants could call with questions. Participants could tailor the written information by choosing topics from a list of 34 topics and the level of information detail (detailed or brief)<sup>27</sup> (please see online [Appendix A for this checklist](#)~~supplementary materials~~) and the verbal sessions by nominating the topics for discussion. Intervention group participants received the written information and face-to-face sessions prior to discharge interview (please see online [Appendix B and C for the Intervention Protocol and Intervention Templates](#)~~supplementary materials~~). Following discharge, telephone contact to participants was provided by three health professional-initiated telephone calls at intervals of approximately one month, over a three month period (please see ~~online~~ [Appendix B](#)~~supplementary materials and C~~). As the Health Belief Model<sup>20</sup> and adult learning principles<sup>22</sup> was used to inform the development of the intervention, the health professional providing the intervention incorporated the following strategies where possible: assessing knowledge, exploring barriers and ways to overcome them; correcting misinformation; providing specific and personalised information about the risks and

seriousness of unhealthy behaviour, and specific details of the benefits of healthy behaviour; providing reassurance and encouraging the use of support networks; using persuasion and training in breaking tasks into smaller steps; and encouraging the use of stress management strategies.

The health professional providing the intervention was not a member of the interdisciplinary team at either stroke unit and approached participants independent of the standard treating team. Face-to-face sessions were conducted at the patients' bedside or in a nearby quiet interview room. In the case of participating dyads (both patient and their carer allocated to the intervention group), participants were offered the choice of combined or separate education sessions. The information needs checklist, intervention protocol and the intervention tracking template are provided as online supplementary materials. Further details of the intervention are available from the author on request.

Outcome measures

The primary outcome was stroke knowledge and assessed using the 25-item Knowledge of Stroke Questionnaire<sup>16</sup> which has a true/false/don't know response format and has good test-retest reliability,<sup>28</sup> with higher scores indicating better stroke knowledge. Secondary outcomes were self-efficacy, anxiety and depression, quality of life (patients) and caregiver burden (carers) and ratings of: being informed; importance of information; and satisfaction with information received. Due to a lack of a suitable existing measure, the tool for assessing self-efficacy in accessing and using stroke information that was developed for this study, drawing on Lorig and colleagues' Self-efficacy to Perform Self-Management Behaviour measures for chronic disease.<sup>29</sup> It consists of nine items (see Table 2), each scoring self-



efficacy on a 1-10 Likert scale, and using a stem statement of “At the moment, how confident are you that you...?”

Anxiety and depression was assessed using the 14-item Hospital Anxiety and Depression Scale (HADS)<sup>30</sup> (scores range from 0-21 for each anxiety and depression subscale), with higher scores indicating higher levels of anxiety or depression. The internal consistency, as indicated by Spearman’s correlation, of the HAD’s anxiety subscale items has been reported as ranging from +0.76 to +0.41 ( $p < 0.01$  for all items) and for the depression subscale, +0.60 to +0.30 (all lower than  $p < 0.02$ ).<sup>30</sup> Self-reported ratings of being informed, the importance of information and satisfaction with information received were assessed using 10-point Likert scales, where 1 = “not at all...” and 10 = “extremely...”

Finally, patient-specific quality of life was assessed using the Stroke and Aphasia Quality of Life Scale-39 Generic (SAQOL-39g) which has been validated on patients with and without aphasia.<sup>31</sup> The 39 items, each scored on a Likert scale of 1-5, are organised into three categories: physical, psychosocial and communication. Higher category and total means indicate better quality of life. The SAQOL-39 has acceptable test-retest reliability (intraclass correlation coefficient = 0.89 to 0.98), internal consistency (Cronbach’s  $\alpha = 0.74$  to 0.94), and construct validity (corrected domain-total correlations,  $r = 0.38$  to 0.58; convergent,  $r = 0.55$  to 0.67; discriminant,  $r = 0.02$  to 0.27 validity).<sup>32</sup> A carer-specific measure of burden was assessed using the Caregiver Strain Index (CSI), for which scores range from 0-13 with higher total scores indicating higher burden.<sup>33</sup> It has strong internal consistency (Cronbach’s  $\alpha = 0.86$ ),<sup>33</sup> clinical validity and significant correlation with other caregiver burden scales.<sup>34</sup>

Finally, questions were asked of the intervention group participants to obtain feedback on the intervention. These included asking if they had read the booklet, and the usefulness of each of the four components of the intervention on a 1-10 Likert scale, where 1=“not at all useful” and 10=“extremely useful”.

Sample size and statistical analysis

A sample size calculation was conducted for the primary outcome of stroke knowledge based on data from previous research<sup>16</sup> and on the expectation that a between-group difference of a mean score of 2 would be clinically significant. Assuming equality of groups pre-intervention, using a standard deviation of 3.6, power of 0.8 and a significance level of 0.05 (two-sided), a required sample size of 102 (51 in each group) was predicted. To allow for a possible attrition rate of 25%, a target of 136 participants was set. Statistical analysis was conducted using STATA (version 10) and on an intention-to-treat basis. Because of baseline differences in age between the groups, ANCOVAs were completed on follow-up scores for all outcomes. Participants included both patients and carers, with data analysed together.

**Results**

The flow of participants through the trial is presented in Figure 1. Recruitment occurred over a thirteen month period between 2008 and 2009, during which time 273 patients and 102 available carers were assessed for eligibility. Of the 138 participants randomised, 8 control group participants and 11 intervention group participants were lost to follow-up, resulting in an overall follow-up rate of 86%. Demographic and clinical characteristics of participants are presented in Table 1. Just over half of the participants (55.5%) had their paired patient or

carer also participating in the study. Baseline and follow-up outcome measure scores are presented in Table 2. Participant mean age at baseline was significantly different between the control and intervention groups (61.8 vs. 55.1 years).

At the three month follow-up, there were no significant between-group differences for stroke knowledge. Participants in the intervention group did however, have significantly better: self-efficacy for accessing stroke information (adjusted mean difference (MD) of 1.0, 95% confidence interval (CI) 0.3 to 1.7,  $p=0.004$ ); feeling informed (MD 0.9, 95% CI 0.2 to 1.6,  $p=0.008$ ); and satisfaction with information received relating to medical (MD 2.0, 95% CI 1.1 to 2.8,  $p<0.001$ ); practical (MD 1.1, 95% CI 0.3 to 1.9,  $p=0.008$ ), services and benefits (MD 0.9, 95% CI 0.1 to 1.8,  $p=0.036$ ); and secondary prevention (MD 1.7, 95% CI 0.9 to 2.5,  $p<0.001$ ) (see Table 2). There were no significant between-group differences for the other outcomes.

#### Intervention provision and feedback

The mean number of contacts prior to discharge was 1.3 (SD 0.6, range 1-3) and 2.5 (SD 0.9 range 0-3) following discharge. The mean total minutes of contact prior to discharge was 25.5 (SD 14.9, range 2-60) and following discharge was 8.6 (SD 8.3, range 1-43). The mean length of total contact time (face-to-face and telephone) was 59.1 minutes (SD 40.0, range 9-196). Only one participant (a patient) made use of the telephone support number to contact the health professional with a question. Please see Table 3 which presents the proportion of participants who reported each component of the intervention as useful and the mean usefulness rating. Fifty-five (91.7%) of participants in the intervention group stated that they

had read the written booklet. [There were no differences between patients and carers in the use and satisfaction with the intervention \(data not shown\).](#)

**Discussion**

The provision of a tailored education and support package to stroke patients and carers resulted in participants reporting significantly higher self-efficacy for accessing stroke information, feelings of being informed, and satisfaction with information received. Strengths of this study include: it's randomised controlled design; an intervention whose design was informed by a series of previous studies with the intended population; and the inclusion of both patients and carers which enhances the applicability to health professionals working in this clinical area. It is noted that this combined analysis does not allow separation of patient and carer outcomes, which may be of interest to clinicians and researchers [\(please see online Appendix D which details separate patient and carers scores at baseline and follow-up\)](#). Both patients and carers were recruited as participants for this study as the intervention was designed to meet the needs of both patients and carers and this also allowed maximization of the power of the study.

A limitation of this study is that these results may not be generalisable to patients with more severe cognitive impairment or aphasia or to patients who require high-level residential care and their carers. These populations are commonly excluded from studies of educational interventions and identifying effective educational resources, as well as methods by which to conduct this research are current research gaps. Under powering and the possibility of a Type

II error should also be considered. Finally, a three month follow-up period may also not have been sufficient to see the full influence of the intervention.

Our study used a 25-item stroke knowledge test, which allowed comparison with the previous RCT of the tailored written booklet used as part of the current study's intervention.<sup>16</sup>

Hoffmann and colleagues found a non-significant between-group difference of 0.1,<sup>16</sup> while for this study it was 0.9, yet also non-significant.. A significant improvement in knowledge in the intervention group had been found by Lowe et al.<sup>15</sup> The content of Lowe's booklets contained both general and patient-specific stroke information, while the content of our booklets was entirely tailored by the participants' choice of content and level of information. This more complete tailoring may make it difficult to accurately assess the knowledge of all participants using a uniform measure as not all participants will have been exposed to the same content. Use of a knowledge outcome measure that is more sensitive to differing content exposure or variations to the intervention (such as greater intensity) may be required to detect differences achieved from a tailored intervention.

Insufficient intensity of the intervention may have also contributed to the lack of significant differences between the groups for the other outcomes, along with underpowering of the study. Although a total of up to six contacts with the health professional providing the intervention were offered, some participants declined some of these. This may have diluted the effect of the intervention. Possible explanations for the amount of post-discharge contact being considerably less than the amount of pre-discharge contact include: reduced tolerance for long telephone conversations due to stroke-or carer-related fatigue; difficulty engaging some participants in discussion over the telephone; or needs other than information taking a

higher priority once a patient has left the acute ward. Additionally, although care was taken to ensure the telephone contacts occurred at times suitable to the participant, participants may have felt that they did not have ‘time to talk’ or were not as prepared for the discussion as they could have been. This emphasises the need to complete a regular, formal review of information needs.<sup>18, 35</sup> Formalising the information provision by scheduling an outpatient appointment may overcome some barriers of telephone communication, but may create other difficulties for patients and carers such as community mobility. The use of alternative communications such as computer-based video-conferencing may be more resource- and time-efficient, and more convenient for patients and/or carers who experience difficulties with community mobility and transport post-stroke. Alternative solutions should be explored, depending on the resources and infrastructure available to stroke patients, their carers, and the health facility in which the health professionals work. Information needs persist and change beyond hospital discharge<sup>4, 36</sup> and health professionals need to find ways to continually meet these changing needs.

In the current study participants in the intervention group had significantly better self-efficacy for accessing stroke information. Several components of the intervention may have directly contributed to this, including: the written information booklet contained a detailed ‘Where to get help’ section, and the health professional providing the intervention modelled strategies which encouraged the use of support networks and explored barriers to accessing them and ways overcome these. Several health education theories describe self-efficacy as an important precursor to performance of a task.<sup>20</sup> This has important implications for the abilities of patients with stroke and their carers to meet ongoing information needs, as it suggests that the intervention may empower them to independently access stroke information even after the

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3 intervention period ceased. Facilitating self-efficacy has been found to improve longer-term  
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5 health outcomes in patients with chronic health conditions.<sup>37</sup>  
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10 In the current study participants in the intervention group also demonstrated better  
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12 satisfaction than control group participants. Higher satisfaction was also found by Hoffmann  
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14 et al.<sup>16</sup> The intervention group participants rated all four intervention components highly,  
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16 including the post-discharge options of talking to someone over the telephone and having a  
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18 telephone support person available if needed. A Cochrane review of health professional-  
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20 initiated telephone contact with patients following hospital discharge concluded that the  
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22 effect of this medium on patient outcomes is currently inconclusive.<sup>38</sup> While this review  
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24 included studies which involved patients from various diagnostic groups, it did not include  
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26 any studies specifically with stroke patients. The needs of stroke patients and their carers  
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28 post-discharge differ quite substantially to those of other patient groups and stroke-specific  
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30 studies evaluating this are needed. Stroke patients and carers have reported satisfaction with  
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32 receiving telephone support when provided in combination with face-to-face provision<sup>39</sup> and  
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34 a desire to receive telephone support as a follow-up to face-to-face provision.<sup>40</sup>  
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41 The high ranking of the usefulness of having someone to call with questions was surprising  
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43 given that this option was utilised by only one participant. It may be that participants did not  
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45 use this option because the health professional who provided the intervention appropriately  
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47 elicited and addressed information needs during the health professional-initiated contacts, or  
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49 that intervention group participants accessed other sources of information to ask additional  
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51 questions. Nevertheless, it appears that participants in this study were satisfied to know that  
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53 there was someone to call, even if they did not utilise the service. Whether this 'call in'  
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55 component of the intervention would have been better utilised had the follow-up period been  
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longer is also unknown. The need to provide contact details for any questions that may arise following discharge is acknowledged in national and international stroke care guidelines.<sup>2, 3,</sup>  
<sup>41</sup>Appropriate post-discharge support and/or contact is often identified as a gap in services, by both patients and carers<sup>8</sup> and hospitals which provide stroke care,<sup>42</sup> and it would be of interest.

Given the lack of effect on most of the outcome measures used in this study, it needs to be considered whether the improvement that was found in some outcomes is sufficient to justify the implementation of the intervention. Whether a stroke support service should continue to be funded if it does not address psychosocial outcomes has been raised in a previous study of stroke family officers support officers.<sup>43</sup> While the resources required to provide this intervention are less intensive than many of the other stroke patient and carer education and support interventions that have been trialled, a cost effectiveness evaluation of this intervention, following refinement of some of its features, is required.

Areas for future research

A qualitative component of this study may have enhanced interpretation of the quantitative results and provided further insights into participants’ perspectives about components of the intervention. Outcome measures relating to self-efficacy, satisfaction and ratings of the importance of information and feeling informed were developed for this study due to a lack of existing measures and exploration of their psychometric properties, sensitivity to change, and their suitability for people with aphasia would be valuable.



Enhancement of the intervention may be needed to influence psychosocial outcomes. This enhancement may come from combining its provision with other active informational interventions. For example, hands-on practical training for carers has been demonstrated to reduce in patient anxiety and depression and carer anxiety, depression and burden.<sup>44</sup> A recent systematic review of educational needs of patients with stroke and their carers calls for improvements in stroke education.<sup>4</sup> Enhancement and provision of this tailored stroke education and support package may be one way of addressing this need.

## Conclusion

The provision of a tailored education and support package resulted in significantly higher self-efficacy in accessing stroke information, feelings of being informed, and satisfaction with information received of stroke patients and their carers. Refinement and enhancement of the package and subsequent evaluation of its effect is required before widespread implementation can be recommended.

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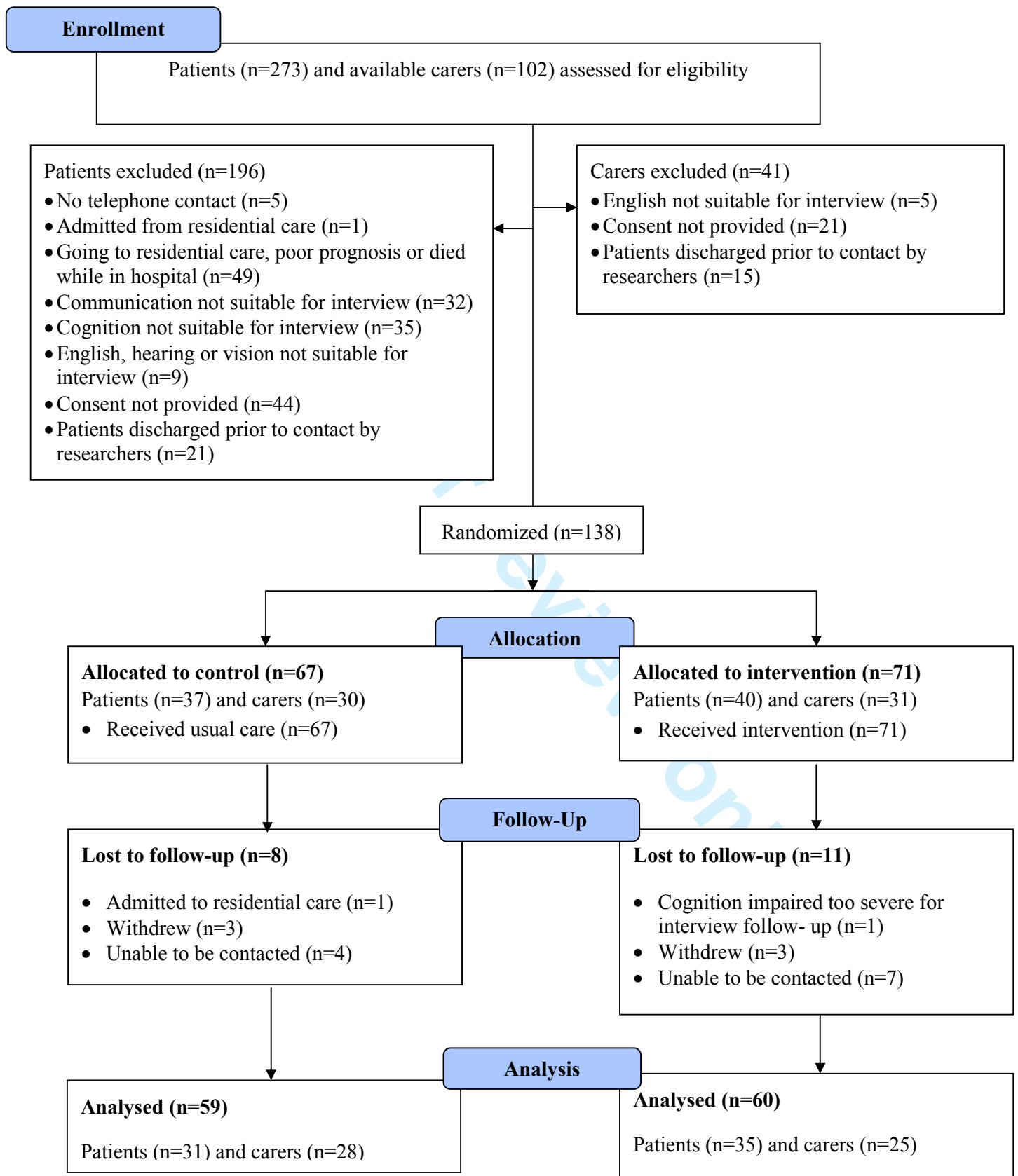
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**Figure 1:** Flow of participants

**Table 1:** Demographic and clinical characteristics at baseline. Values are numbers (percentages) unless otherwise stated

Variable	Control (n=67)	Intervention (n=71)
Mean age in years (SD; range)	61.4 (12.7; 24-86)	55.2 (16.7; 27-97)
Female gender	36 (53.7)	39 (54.9)
Living with:		
Alone	10 (14.9 )	13 (18.3)
Partner / family	57 (85.1)	58 (81.7)
Relationship to patient <sup>a</sup>	(n=30)	(n=31)
Partner	21 (70.0)	20 (64.5)
Child	7 (23.3)	9 (29.0)
Sibling/other	2 (6.7)	2 (6.5)
Mean years of schooling (SD; range)	11.8 (3.6; 2-21)	12.1 (3.3; 6-20)
REALM grade equivalent: <sup>b</sup>	(n=62)	(n=67)
≤ 3rd	0	1 (1.5%)
4 <sup>th</sup> -6 <sup>th</sup>	3 (4.8)	3 (4.5)
7 <sup>th</sup> -8 <sup>th</sup>	19 (30.6)	19 (28.4)
≥9 <sup>th</sup>	40 (64.5)	44 (65.7)



**Table 1 continued:** Demographic and clinical characteristics at baseline

Patient stroke type: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Ischaemic	31 (86.1)	29 (72.5)
Haemorrhagic	5 (13.9)	10 (25)
TIA	0	1 (2.5)
Patient side of stroke: <sup>c</sup>	(n=36) <sup>d</sup>	(n=40)
Left	12 (33.3)	15 (37.5)
Right	21 (58.3)	24 (60.0)
Bilateral	3 (8.3)	1 (2.5)
First-time stroke <sup>c</sup>	(n=37)	(n=40)
	31 (83.8)	27 (67.5)

<sup>a</sup> Carer participants only

<sup>b</sup> Eight patients and one carer were unable to complete the REALM due to poor vision

<sup>c</sup> Patient participants only

<sup>d</sup> One patient's stroke type and side was missing

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**Table 2:** Baseline and 3 month follow-up outcome measures scores

Outcome (score range)	Mean (SD) baseline scores		Mean (SD) follow-up scores		ANCOVA results	
	Control group (n=59)	Intervention group (n=60)	Control group (n=59)	Intervention group (n=60)	Between group difference adjusted mean (95% CI)	p-value
Stroke knowledge (0-25)	17.2 (3.9)	17.5 (3.1)	18.7 (3.5)	19.8 (3.0)	0.9 (-0.4 to 2.2)	0.176
Self-efficacy (1-10)						
Cope with stroke	6.8 (2.6)	7.1 (2.3)	7.7 (1.9)	8.1 (1.8)	0.2 (-0.5 to 0.8)	0.600
Access practical help	7.8 (2.3)	8.2 (2.0)	8.3 (1.9)	8.5 (1.5)	0.2 (-0.4 to 0.9)	0.483
Access emotional help	7.8 (2.4)	8.0 (2.1)	8.1 (2.0)	8.0 (2.1)	0.0 (-0.7 to 0.9)	0.909
Manage stress	7.2 (2.3)	7.5 (2.2)	7.3 (2.1)	7.6 (1.7)	0.2 (-0.5 to 0.9)	0.584

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

**Self-efficacy (1-10) continued**

Access stroke information	7.6 (2.5)	7.8 (2.4)	7.8 (2.2)	8.8 (1.4)	1.0 (0.3 to 1.7)	0.004*
Understand stroke information	7.9 (1.9)	7.9 (2.1)	7.9 (1.9)	8.5 (1.4)	0.6 (-0.1 to 1.2)	0.077
Talk with doctor	8.6 (2.0)	8.9 (1.4)	8.7 (1.5)	8.9 (1.7)	0.1 (-0.5 to 0.8)	0.651
Talk with health professionals	8.5 (1.8)	8.7 (1.8)	8.6 (1.6)	8.7 (1.6)	0.2 (-0.4 to 0.8)	0.567
Prevent (another) stroke	7.0 (2.4)	6.9 (2.7)	6.8 (2.2)	7.3 (2.7)	0.2 (-0.7 to 1.2)	0.608
<b>Anxiety (0-21)</b>	7.5 (4.2)	8.7 (4.5)	6.6 (4.3)	7.3 (4.3)	0.5 (-1.1 to 2.1)	0.559
<b>Depression (0-21)</b>	5.0 (3.4)	5.4 (3.8)	4.3 (3.5)	4.9 (3.6)	0.6 (-0.7 to 2.0)	0.377
<b>Feeling informed (1-10)</b>	6.1 (2.6)	6.0 (2.3)	7.3 (1.9)	8.2 (1.7)	0.9 (0.2 to 1.6)	0.008*
<b>Importance of information (1-10)</b>	9.9 (0.4)	9.6 (1.2)	9.4 (1.4)	9.5 (1.1)	0.1 (-0.4 to 0.6)	0.615

**Table 2 continued:** Baseline and 3 month follow-up outcome measures scores

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<b>Satisfaction with information received (1-10)</b>						
Medical information	6.3 (2.5)	6.5 (2.3)	6.8 (2.6)	8.8 (1.8)	2.0 (1.1 to 2.8)	<0.001*
Practical information	5.9 (2.7)	6.2 (2.7)	7.4 (2.5)	8.5 (1.9)	1.1 (0.3 to 1.9)	0.008*
Service and benefits	5.3 (3.0)	5.8 (2.8)	7.1 (2.7)	7.9 (1.8)	0.9 (0.1 to 1.8)	0.036*
Prevention information	5.8 (2.7)	6.2 (2.7)	6.9 (2.6)	8.6 (1.7)	1.7 (0.9 to 2.5)	<0.001*
<b>Quality of life (patients) (1-5)</b>	(n=31)	(n=35)	(n=31)	(n=35)	0.1 (-0.2 to 0.4)	0.496
	3.5 (0.8)	3.6 (0.8)	4.1 (0.7)	4.0 (0.7)		
<b>Caregiver burden (carers) (0-13)</b>	(n=28)	(n=25)	(n=28)	(n=25)	0.1 (-2.0 to 2.1)	0.932
	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)		

\* significant difference between groups      ^ f-value indicated underpowering likely

**Table 3:** Satisfaction with intervention components

Intervention component	Participant reported component as useful n (%) (n=60 )	Mean (SD) usefulness rating (1-10)
Written component	53 (88.3)	9.1 (1.4)
Talking to someone face-to-face (in hospital)	58 (96.7)	8.9 (1.6)
Talking to someone over the telephone (following discharge)	45 (75.0)	7.9 (2.3)
Having a telephone support person available if needed	51 (85.0)	8.2 (2.4)

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**Authors’ contribution**

Dr Eames was partially responsible for concept design, and primarily responsible for review of the literature, participant recruitment, data collection, data analysis and interpretation and manuscript preparation. A/Prof. Hoffmann and Prof. Worrall were partially responsible for concept design and also provided peer-review of data analysis and interpretation and manuscript preparation. Dr Read and Dr Wong provided peer-review of data interpretation and manuscript preparation.

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**Data sharing statement**

The dataset is available at Dryad repository (provisional doi:10.5061/dryad.hs03q), who will provide a permanent, citable and open access home for the dataset.

## Appendix

Appendix A “What *you* need to know about stroke” checklist

Appendix B Intervention protocol

Appendix C Intervention template

Appendix D Separate patient and carer scores

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Appendix A “What *you* need to know about stroke” checklist

(Please see attached file.)

For peer review only



Appendix B Intervention protocol

For peer review only

**Intervention Protocol – Stroke information service**

Prior to discharge:

First contact will occur prior to Acute Stroke Unit (ASU) discharge, after the initial interview is completed.

- It will involve an introduction to the tailored written education booklet (participants will be shown an example) and participants’ selection of topics of interest to them.
- One copy will be printed for each client (paired clients and carers will have one between two unless specifically requested – highlighting sections that were ‘client or carer only requested’).

On second contact the booklet will be provided and layout will be briefly explained.

- Content will be discussed, with a particular focus on keys areas (such as risk factors and behaviours to address these) and any questions answered.
- Explanation of the scope and limits of the intervention will be provided.
- Participants will then be offered a third face-to-face session to discuss the information and/or ask questions after they have had time to read the booklet.
- A suitable day/time for the first follow-up telephone call (approximately 3-4 weeks later) will be confirmed, with a prompt to look through the booklet before the telephone call to remind themselves of any questions and to have booklet at hand during the telephone call.
- Participants will be provided with the support service’s contact telephone number if they need to contact the service in the interim, in addition to reinforcement of other suitable contacts (for example, their GP, service providers, treating team).
- If clients are discharged before this visit, the written education booklet will be posted out and a telephone call made to the participant a few days after its arrival.

After ASU discharge:

The first telephone follow-up call will be made to participant approximately 3-4 weeks post ASU discharge

- Verbal reinforcement of the content of booklet will occur (all/some of topics, as per client preference/needs) with a particular focus on risk factors and behaviours to address these.
- Any questions from the book/in general will be answered.
- A suitable time for the second follow-up call (in approximately 1 month) will be made, with a prompt to look through the booklet before the telephone call to remind themselves of any questions and to have booklet at hand during the telephone).
- Confirmation of the support services' contact telephone number if they need to call in the interim and reinforce other suitable contacts (their GP, service providers, treating team).

Second follow-up telephone call:

- ~Verbal reinforcement of content of booklet (all/some of topics - as per client preference/needs) with a particular focus on risk factors and behaviours to address these.
- Any questions from the booklet/in general will be answered.
- Review of information needs. If participants indicate any other topics of interest, these will be posted out to add to booklet.
- Participants will be offered a final call (in approximately 1 month) if desired, and reminded that they can contact the support service for up to three months post ASU discharge.

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Appendix C    Intervention template

For peer review only

Intervention provided		Date	Details								Time taken		
											Direct contact	Indirect contact	
			Didactic	Combo	Ref to written	Q&A	Discussion	Link to services	P/S (modelling)	Role Play	Other		
Checklist of topics (after initial interview and randomisation)													
Booklet printed (and posted)													
<b>1<sup>st</sup> contact face-to-face</b> (after consent and Initial Interview)	Attempts to contact												
	Explanation of lx (what it is and is not)												
	Provision of education booklet with explanation of layout		Booklet posted (____) and lx completed over t/p <input type="checkbox"/>										
	Reinforcement of booklet topics..... AND delivery style used												
<b>2<sup>nd</sup> contact face-to-face</b>	Attempts to contact		Not completed as booklet posted & 1 <sup>st</sup> contact completed over t/p <input type="checkbox"/> OR client d/c prior <input type="checkbox"/>										
	Reinforcement of booklet topics..... AND delivery style used												

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	Questions asked and answered...													
Intervention provided		Date	Details										Time taken	
			Didactic	Combo	Ref to written	Q&A	Discussion	Link to services	P/S (modelling)	Role Play	Other	Direct contact	Indirect contact	
3 <sup>rd</sup> contact face-to-face (optional)	Questions asked and answered...													
	Reinforcement of booklet topics..... AND delivery style used													
	Confirm first t/p follow-up contact day/time (~1/12) AND service ph no for Qs													
	Not completed (client/carer declined) <input type="checkbox"/> OR client discharged <input type="checkbox"/>													
4 <sup>th</sup> contact telephone (3-4 weeks post d/c):	Attempts to contact													
	Questions asked and answered...													
	Reinforcement of booklet topics..... AND delivery style used													

	Confirm next t/p next follow-up contact day/time (~1/12) AND service ph no for Qs													
Intervention provided		Date	Details										Time taken	
			Didactic	Combo	Ref to written	Q&A	Discussion	Link to services	P/S (modelling)	Role Play	Other	Direct contact	Indirect contact	
5 <sup>th</sup> contact telephone (~2 month post d/c):	Attempts to contact													
	Questions asked and answered...													
	Reinforcement of booklet topics..... AND delivery style used													
	Offer final t/p follow-up, confirm contact day/time (~1/12) AND service ph no for Qs													
	If decline final f/u call, clarify date of service cessation and remind of f/u interview arrangements Not completed (client/carer declined) <input type="checkbox"/>													
6 <sup>th</sup> contact telephone (~3 months post d/c; at least 1	Questions asked and answered...													
	Reinforcement of booklet													

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week before f/u interview due):	topics.....												
	AND delivery style												
	Clarify date of service end & remind of f/u IV												

For peer review only



Appendix D Separate patient and carer scores

For peer review only

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Outcome (score range)	Patients				Carers			
	Mean (SD) baseline scores		Mean (SD) follow-up scores		Mean (SD) baseline scores		Mean (SD) follow-up scores	
	Control group (n=31)	Intervention group (n=35)	Control group (n=31)	Intervention group (n=35)	Control group (n=28)	Intervention group (n=25)	Control group (n=28)	Intervention group (n=25)
Stroke knowledge (0-25)	15.6 (3.7)	16.8 (3.0)	17.4 (3.4)	19.3 (2.7)	18.9 (3.4)	18.4 (3.2)	20.2 (3.0)	20.4 (3.3)
Self-efficacy (1-10)								
Cope with stroke	5.9 (3.0)	7.2 (2.5)	7.5 (2.0)	8.1 (1.7)	7.8 (1.6)	7.1 (2.1)	8.0 (1.7)	8.0 (1.9)
Access practical help	7.6 (2.5)	8.5 (1.7)	8.2 (2.0)	8.5 (1.4)	8.0 (2.0)	7.7 (2.4)	8.3 (1.8)	8.5 (1.7)
Access emotional help	7.5 (2.8)	8.0 (2.1)	8.2 (2.1)	8.0 (1.9)	8.2 (1.8)	8.0 (2.1)	8.1 (1.9)	8.0 (2.4)
Manage stress	6.6 (2.8)	7.7 (2.2)	7.1 (2.2)	7.6 (1.8)	7.8 (1.5)	7.3 (2.3)	7.6 (1.9)	7.5 (1.5)

## Appendix D continued

## Self-efficacy (1-10) continued

Access stroke information	7.2 (2.7)	7.6 (2.5)	7.6 (2.3)	8.7 (1.7)	8.1 (2.1)	7.9 (2.2)	7.9 (2.1)	8.9 (1.0)
Understand stroke information	7.5 (2.2)	7.9 (2.3)	7.5(2.0)	8.4 (1.5)	8.3 (1.5)	8.0 (1.7)	8.3 (1.7)	8.5 (1.3)
Talk with doctor	8.4 (2.4)	8.8 (1.4)	8.7 (1.5)	8.9 (1.7)	8.8 (1.6)	9.0 (1.4)	8.8 (1.6)	8.8 (1.8)
Talk with health professionals	8.0 (2.3)	8.5 (1.8)	8.3 (1.9)	8.6 (1.6)	9.1 (1.0)	8.9 (1.8)	9.0 (1.1)	8.8 (1.7)
Prevent (another) stroke	7.6 (2.4)	7.4 (2.4)	6.4 (2.2)	7.5 (2.6)	6.4 (2.3)	6.1 (2.9)	6.8 (2.2)	6.9 (3.0)
Anxiety (0-21)	6.8 (4.1)	7.0 (3.4)	6.4 (4.6)	6.8 (4.0)	8.3 (4.2)	11.0 (4.7)	6.9 (4.1)	8.1 (4.6)
Depression (0-21)	5.2 (3.8)	4.4 (3.0)	5.0 (4.1)	5.2 (3.7)	4.8 (3.1)	6.7 (4.4)	3.5 (2.5)	4.5 (3.8)
Feeling informed (1-10)	5.7 (3.1)	5.9 (2.6)	7.1 (2.3)	8.3 (1.8)	6.5 (1.8)	6.1 (2.1)	7.6 (1.4)	8.2 (1.6)
Importance of information (1-10)	9.8 (0.5)	9.5 (1.3)	9.2 (1.7)	9.3 (1.3)	9.9 (0.3)	9.7 (1.1)	9.6 (0.8)	9.7 (0.9)

Appendix D continued

<b>Satisfaction with information received (1-10)</b>								
Medical information	6.2 (2.9)	6.9 (2.4)	6.6 (2.9)	8.6 (1.9)	6.4 (1.8)	6.0 (2.1)	7.0 (2.2)	9.0 (1.7)
Practical information	6.1 (2.8)	6.7 (2.7)	7.6 (2.2)	8.5 (1.6)	5.6 (2.7)	5.4 (2.6)	7.1 (2.7)	8.4 (2.2)
Service and benefits	5.4 (3.0)	6.6 (2.6)	7.0 (2.8)	7.8 (1.7)	5.2 (3.2)	4.7 (2.8)	7.3 (2.6)	8.1 (1.9)
Prevention information	5.9 (2.7)	6.9 (2.3)	7.2 (2.5)	8.7 (1.6)	5.7 (2.7)	5.2 (3.0)	6.6 (2.7)	8.4 (1.8)
<b>Quality of life</b> (patients) (1-5)	3.5 (0.8)	3.6 (0.9)	4.0 (0.7)	4.0 (0.7)	N/A	N/A	N/A	N/A
<b>Caregiver burden</b> (carers) (0-13)	N/A	N/A	N/A	N/A	4.8 (2.9)	5.8 (3.4)	6.2 (3.7)	6.5 (3.4)



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6-7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6-7,
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7

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3		11b	If relevant, description of the similarity of interventions	7
4	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
5		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
6				
7	<b>Results</b>			
8	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
9	diagram is strongly		were analysed for the primary outcome	
10	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	11 & 21
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
12		14b	Why the trial ended or was stopped	N/A
13				
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	21-22
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	21
16			by original assigned groups	
17				
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	24-26
19	estimation		precision (such as 95% confidence interval)	
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	N/A
22			pre-specified from exploratory	
23				
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
25				
26	<b>Discussion</b>			
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-16
30				
31	<b>Other information</b>			
32	Registration	23	Registration number and name of trial registry	2 & 7
33	Protocol	24	Where the full trial protocol can be accessed, if available	N/A
34	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	28
35				

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37 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

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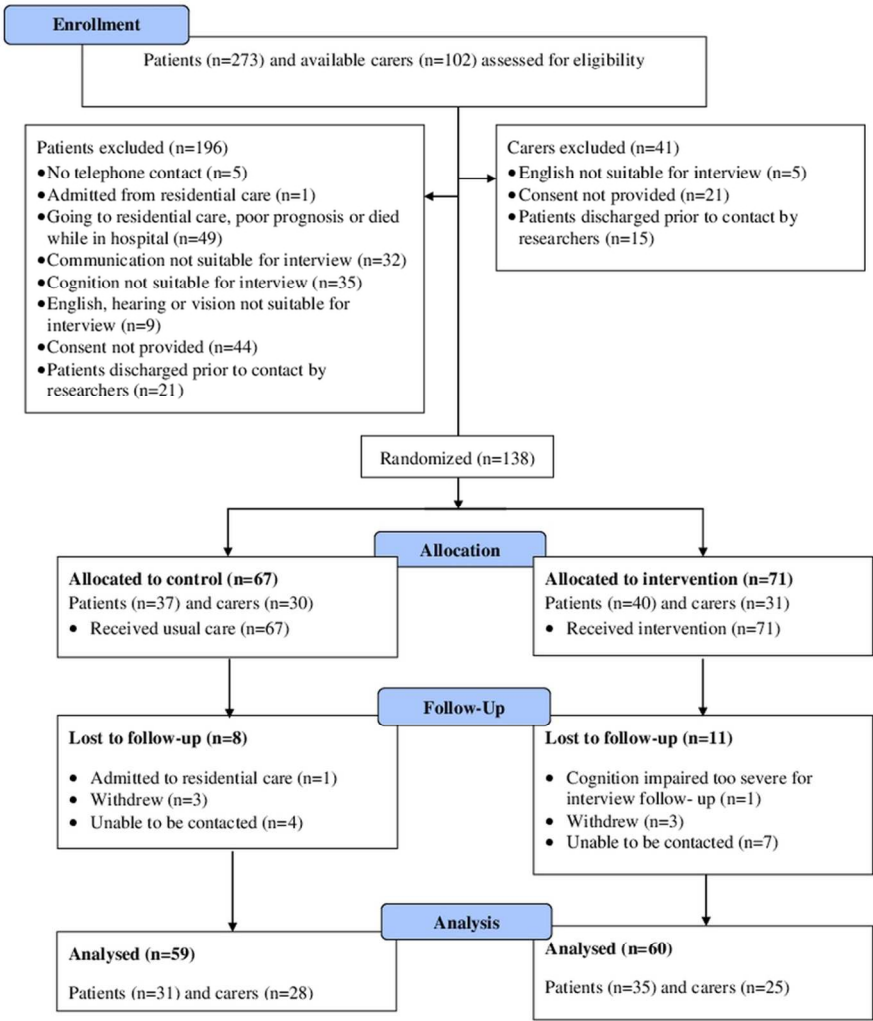
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# Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of the study as randomized	1
Authors *	Contact details for the corresponding author	Separate attachment
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	1
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	1
Interventions	Interventions intended for each group	1
Objective	Specific objective or hypothesis	1
Outcome	Clearly defined primary outcome for this report	1-2
Randomization	How participants were allocated to interventions	1
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	1
Results		
Numbers randomized	Number of participants randomized to each group	1
Recruitment	Trial status	1
Numbers analysed	Number of participants analysed in each group	1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	2
Harms	Important adverse events or side effects	N/A
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	2
Funding	Source of funding	End of article

*\*this item is specific to conference abstracts*

Figure 1: Flow of participants



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